EXHIBIT 13

Signal Extraction Pulse Oximetry
Rainbow Pulse CO-Oximetry

Bibliography

Masimo SET® Pulse Oximetry Bibliography

In 1989, Masimo invented Signal Extraction Technology (SET) Pulse Oximetry, which enables the use of adaptive filter and parallel processing engine technology to extract the arterial signal from noise. In 1998, Masimo unveiled this breakthrough technology to the world; the first pulse oximetry technology with FDA clearance for motion accuracy claims. And in June 1999, Masimo SET became the first to receive FDA 510(k) clearance with indications for use during motion and low perfusion conditions on all patients. In 2005, Masimo released the Masimo SET with Rainbow Technology CO-Oximeter platform, a new technology that represents the latest in system theory and adaptive signal processing. Rainbow SET, based on Masimo SET technology, uses multiple (7+) distinct wavelengths of light, giving clinicians the ability to non-invasively and continuously measure carboxyhemoglobin (SpCO®) and methemoglobin (SpMet™), together with the unmatched accuracy of Masimo SET SpO_2, Pulse Rate, and Perfusion Index (PI). The ability to obtain these measurements noninvasively and continuously will facilitate earlier detection of compromised oxygenation status for more timely, effective treatment decisions. These initial parameters available on the Rainbow platform are expected to be augmented by the future availability of additional parameters. Please refer to the Masimo Rainbow SET bibliography for article summaries that demonstrate the pervasiveness and prevalence of these life-threatening dyshemoglobins.

Prior to the introduction of Masimo SET, pulse oximeters could only be relied upon for accurate measurement during ideal conditions. Today, after 11 years of clinical research, over 100 independent and objective published clinical studies have shown that Masimo SET reliably and continuously tracks changes in arterial oxygen saturation and pulse rate during motion and low perfusion on all patients in all settings; giving clinicians accurate monitoring when they need it most.

These published studies have concluded that Masimo SET is significantly better than all other pulse oximeters and the only one delivering on the promise of accurate monitoring during motion and low perfusion. Forty-five of these studies have been summarized in this bibliography (color coded in red). The remaining citations are included for the clinician who is interested in the ever increasing depth of the Masimo SET validation evidence-base. A cursory review of these articles (easily accessed via Masimo's website www.masimo.com) demonstrates an overwhelming clinical and scientific endorsement of Masimo SET as the preferred standard in pulse oximetry.

Guide to Study Content

Red indicates that the study is summarized herein.

Study No.	COHb/ MetHb	SpHb	ARM	PVI	Motion	Low Perfusion	Blue Sensor	Improved Outcomes/ Cost	Accuracy/ CO-Oximetry	OR, PACU, ICU	NICU, PICU, Peds	PI	Forehead and/ or Ear sensors	Sleep	EMS/ Transport/ Resuscitation
1								●			●	●			
2		●							●						
3			●						●	●					
4			●						●		●				
5				●				●							●
6							●	●	●		●				
7							●		●		●				
8	●							●							
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15			●						●	●					
16					●			●	●		●				
17											●				
18								●			●				●
19									●						
20			●						●	●					
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MASITC_01112005

Study No.	COHb/ MetHb	SpHb	ARM	PVI	Motion	Low Perfusion	Blue Sensor	Improved Outcomes/ Cost	Accuracy/ CO-Oximetry	OR, PACU, ICU	NICU, PICU, Peds	PI	Forehead and/ or Ear sensors	Sleep	EMS/ Transport/ Resuscitation
30					●	●									
31					●	●									
32					●	●									
33	●								●						
34								●				●			
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42	●														
43					●	●			●		●				
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58								●	●		●				

MASITC_01112006

Study No.	COHb/ MetHb	SpHb	ARM	PVI	Motion	Low Perfusion	Blue Sensor	Improved Outcomes/ Cost	Accuracy/ CO-Oximetry	OR, PACU, ICU	NICU, PICU, Peds	PI	Forehead and/ or Ear sensors	Sleep	EMS/ Transport/ Resuscitation
59												●			
60												●			
61					●						●				
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MASITC_01112007

Study No.	COHb/ MetHb	SpHb	ARM	PVI	Motion	Low Perfusion	Blue Sensor	Improved Outcomes/ Cost	Accuracy/ CO-Oximetry	OR, PACU, ICU	NICU, PICU, Peds	PI	Forehead and/ or Ear sensors	Sleep	EMS/ Transport/ Resuscitation
88						●			●	●					
89					●	●									
90					●	●					●				
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MASITC_01112008

Study No.	COHb/ MetHb	SpHb	ARM	PVI	Motion	Low Perfusion	Blue Sensor	Improved Outcomes/ Cost	Accuracy/ CO-Oximetry	OR, PACU, ICU	NICU, PICU, Peds	PI	Forehead and/ or Ear sensors	Sleep	EMS/ Transport/ Resuscitation
117						●					●				
118									●		●			●	●
119														●	
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MASITC_01112009

Study No.	COHb/ MetHb	SpHb	ARM	PVI	Motion	Low Perfusion	Blue Sensor	Improved Outcomes/ Cost	Accuracy/ CO-Oximetry	OR, PACU, ICU	NICU, PICU, Peds	PI	Forehead and/ or Ear sensors	Sleep	EMS/ Transport/ Resuscitation
145					●				●		●				
146					●										
147						●					●				
148								●			●				
149					●	●					●				
150					●									●	
151					●	●					●				
152					●	●									●
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156						●			●						
157					●						●				
158					●	●					●				
159						●				●					
160					●										
161					●										
162						●									
total studies by topic	11	4	5	1	61	50	7	30	39	21	65	15	9	15	8

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Red indicates that the study is summarized herein.

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1 Noninvasive Peripheral Perfusion Index as a Possible Tool for Screening for Critical Left Heart Obstruction.

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Introduction

Congenital heart disease affects seven to eight of every 1000 newborns, resulting in 3% of all infant mortalities most of which occur in the first year of life[1] so early detection and treatment is critical. In addition, up to 30% of all deaths from congenital heart disease in the first year of life are due to failure to detect the condition. Oxygen saturation readings from pulse oximetry have been used for the early detection of duct dependent congenital heart disease in infants with high sensitivity and specificity[2] but this method is less accurate for detecting cases with duct-dependent systemic circulation. Researchers from the Department of Clinical Sciences at the Sahlgrenska Academy in Sweden report on a new method, using Masimo SET Perfusion Index (PI), to detect Left Heart Obstructive Disease, (LHOD) a type of congenital cardiac defect that could not be accurately detected previously by physical examination or with pulse oximetry.

Methods

Ten thousand healthy newborns and nine infants with LHOD, all between 1-120 hours of age and recruited from all newborn nurseries in the fifth cities of Vastra Gotaland Sweden, participated in the study. To establish the range of PI values in healthy newborns compared to the range of PI values from newborns with LHOD, PI readings from the right hand (preductal) and foot (postductal) of both healthy subjects and LHOD patients were taken with a Masimo SET Radical. Preductal and postductal PI measurements were made in addition to saturation screening and neonatal physical exams. None of the infants assigned to the healthy control group were readmitted with duct dependent heart disease within three months of the initial screening. Since the PI distribution curve is different from a normal distribution, results from the statistical analysis of the data were expressed in medians with an interquartile range for non-normal distributions.

Results

All nine LHOD infants had either pre or postductal PI below the interquartile range of the healthy infants and 56% of them had either pre or postductal PI values below the fifth percentile cut off of 0.70. A pre or postductal PI value of below 0.70 increased the likelihood of having LHOD by 23.75%. Among the nine infants diagnosed with LHOD, three cases were missed by neonatal exam and two of these three were missed by screening with pulse oximetry saturation values.

Discussion

Perfusion index from Masimo SET pulse oximetry reflects real time changes in peripheral blood flow at the sensor site and therefore is a direct indicator of arterial circulation. This is the first study to establish a range of PI values for normal infants. Previous studies have shown low PI to be associated with illness in newborns[3], but this is the first study to show that subnormal PI values may be an indicator of duct dependent systemic circulation as occurs with LHOD.

Authors' Conclusions

"Lower PI values than 0.70 may indicate illness. Including the cut off values for PI in pulse oximetry screening for duct-dependent congenital heart disease is a promising tool for improving the detection of critical congenital heart disease with duct-dependent systemic circulation."

1. Thangaratinam S, Daniels J, Ewer AK, Zamora J, Khan KS. Accuracy of pulse oximetry in screening for congenital heart disease in asymptomatic newborns: a systematic review. *Arch Dis Child Fetal Neonatal Ed.* 2007;92:F176-80.
2. de Wahl Granelli A, Mellander M, Sunnegardh J, Sandberg K, Ostman-Smith I. Screening for duct-dependant congenital heart disease with pulse oximetry: a critical evaluation of strategies to maximize sensitivity. *Acta Paediatr.* 2005;94:1590-6.
3. De Felice C, Latini G, Vacca P, Kopotic RJ. The pulse oximeter perfusion index as a predictor for high illness severity in neonates. *Eur J Pediatr.* 2002;161:561-2.

2

Non-Invasive Measurement of Continuous Hemoglobin Concentration Via Pulse CO-Oximetry.

Macknet MR, Kimball-Jones PL, Applegate RL, Martin RD, Allard MW. *Anesthesiology.* 107; A1545.

Introduction

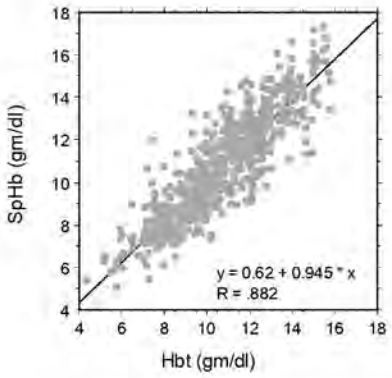
Serial blood draws for the measurement of hemoglobin concentration are standard practice in major surgery, trauma, anemia and dialysis patients but is invasive and time consuming. A device that would allow for continuous real-time, non-invasive monitoring of hemoglobin concentration in these patients and others has the potential to improve clinical care, patient safety and the cost of care. In this study, Macknet and researchers from Loma Linda Medical Center test the accuracy of the prototype Masimo noninvasive total hemoglobin monitor in surgery patients and healthy volunteers compared to invasive CO-Oximetry analysis.

Methods

The accuracy of the prototype Masimo hemoglobin monitor was tested in 30 surgery patients and 18 healthy volunteers. Individuals from both groups were monitored according to ASA standards and fitted with a radial artery cannula and three Masimo prototype total hemoglobin sensors, optically isolated from each other and connected to a data collection system. The healthy volunteers underwent a hemodilution protocol, which consisted of replacing one unit of blood with 30 ml/kg of saline. Data was collected during surgery or during the hemodilution protocol. Readings from the noninvasive hemoglobin sensors (SpHb) were compared to readings from arterial blood gas draws taken at the same time [Hb]. Bias, precision and A_{RMS} were calculated from the 802 data pairs comparing laboratory CO-Oximeter readings to the SpHb readings.

Results

Mean [Hb] +/- SD	10.7 (+/- 2.2)
Range [Hb]	4.4 - 15.8 g/dl
Bias SpHb to [Hb]	0.03
Precision SpHb to [Hb]	1.12
% A_{RMS}	1.12



Authors' Conclusion

"This device is the first device developed that can continuously and noninvasively measure hemoglobin concentration in addition to the other common hemoglobin species and therefore provides a significant expansion to existing physiologic monitoring technology. Rapid measurement of hemoglobin would be extremely useful in many clinical scenarios. This technology in combination with methemoglobin and carboxyhemoglobin measurements should allow for significant advances in patient care."

5 New Algorithm for Automatic Estimation of the Respiratory Variations in the Pulse Oxymeter Waveform.

Cannesson M, Delannoy B, Morand A, Bastien O, Lehot J. *Anesthesiology.* 2007; 107: A451.

Introduction

Decreased ventricular preload (ventricular filling) in critically ill patients may indicate hypovolemia which can be treated by volume expansion. Fluid therapy does not result in increased stroke volume in all patients however. In nonresponsive patients, fluid administration may induce cardiopulmonary complications and hamper tissue healing. Respiratory variation in pulse pressure (ΔPP) has been established as a dynamic variable of ventricular preload but there is currently no accepted method for continuously and noninvasively measuring ventricular preload or ΔPP to guide fluid management. This study tests the ability of Masimo's Pleth Variability Index (PVI) measurement to noninvasively reflect changes in ventricular preload in vascular surgery patients under mechanical ventilation. In addition, it was posited that changes in PVI can be used as a noninvasive method for detecting hypovolemia and guiding fluid therapy.

Methods

Twenty vascular surgery patients, after induction of anesthesia and under mechanical ventilation were used for the study. Each patient had a radial arterial catheter for measuring mean arterial pressure (MAP), an internal jugular vein catheter for measuring central venous pressure (CVP) and wore a Masimo LNOP finger sensor attached to a Radical-7 pulse oximeter for measuring PVI. MAP and CVP were recorded at baseline and while patients were in head-down and head-up positions. PVI was continuously recorded. Respiratory variations in the arterial pulse pressure (ΔPP) was calculated from the maximum and minimum arterial pulse pressure during the same respiratory cycle.

Results

Changes in mean arterial pressure (MAP), central venous pressure (CVP), respiratory variations in pulse pressure (ΔPP), and pleth variability index (PVI) induced by changes in body position.

	MAP (mmHg)	CVP (mmHg)	ΔPP (%)	PVI (%)
Baseline	66±11	11±4	13±6	13±7
Anti-Trendelenburg (head up)	60±14*	5±4*	16±7*	18±7*
Trendelenburg (head down)	74±11†	20±6†	10±5†	10±5†

*p<0.05 compared to baseline; †p<0.05 compared to anti-Trendelenburg

There was a significant correlation between changes in PVI and changes in the arterial pulse pressure suggesting that PVI can be utilized as a noninvasive method for detecting hypovolemia.

Authors' Conclusions

"This study is the first to demonstrate the ability of PVI, an index automatically derived from the pulse oxymeter waveform analysis, to detect changes in ventricular preload. This new index has potential clinical applications for noninvasive hypovolemia detection and fluid responsiveness monitoring."

7 New Pulse Oximetry Sensors with Low Saturation Accuracy Claims – A Clinical Evaluation.

Cox PN. *Anesthesiology.* 2007; 107: A1540.

Introduction

Both Masimo and Nellcor claim to have pulse oximetry systems and sensors that are accurate for oxyhemoglobin saturations below 70%, and therefore appropriate for use on congenital cyanotic cardiac disease patients. This claim has previously been unmet by any commercial pulse oximetry technology. This study compares the accuracy of the Masimo Radical with LNOP Blue sensor and the Nellcor N-600 with Max-I LoSat sensor on congenital cyanotic cardiac lesion patients in the ICU.

Methods

Twelve pediatric ICU patients with congenital cyanotic cardiac lesions were monitored with an LNOP digit sensor, an LNOP Blue sensor, each attached to a Masimo Radical, and a Nellcor Max-I sensor with LoSat attached to an N-600. A total of 60 arterial blood gases were obtained as clinically needed and compared to the pulse oximetry readings from the three sensors. A paired t-test was used to compare the A_{RMS} values from each of the three sensors to the blood gas readings. Laboratory CO-Oximetry readings ranged from 85 to 56.1% with a mean of 72.3%.

Results

	Masimo SET Radical with Blue Sensor	Nellcor N-600 and Max-I sensor with LoSat	LNOP Sensor
Mean ± SD	70.5 (7.5)	75.9 (5.6)	75.2 (6.4)
Range %	87 - 52	89 - 61	91 - 57
Bias	-1.91	3.81	1.86
Precision	3.50	5.26	6.24
A_{RMS}	**3.97***	**6.49**	**6.51**
R^2 value	.886	.698	.60

Table 1- The bias, precision, A_{RMS} and regression analysis for the new sensors with low saturation accuracy claims, and the LNOP sensor in 12 children with congenital cyanotic cardiac lesions. Paired t-test of the A_{RMS} shows a significant difference between the Masimo LNOP Blue and the other sensors, $p < 0.001$.

Conclusion and Author's Comment:

Although the N-600 and Max-I sensor with LoSat claims accuracy of 3.0 A_{RMS} in patients with saturations from 60 - 80%, that accuracy claim was not met and the accuracy was not significantly different from the Masimo LNOP sensor on these patients. The Masimo Radical with Blue sensor, on the other hand, claims accuracy of 4.0 A_{RMS} on saturation levels between 60 - 80% and had an accuracy of 3.97. The author concludes, "Despite advances in technology, only the Masimo Blue sensor demonstrates acceptable accuracy as demonstrated by a smaller bias and precision and A_{RMS}."

9

A Comparison of Finger, Ear and Forehead SpO_2 on Detecting Oxygen Desaturation in Healthy Volunteers.

Tokuda K, Hayamizu K , Ogawa K, Hirai T, Irita K. *Anesthesiology.* 2007; 107: A 1544.

Introduction

Forehead reflectance oximetry has been marketed as having a faster response to changing oxygen saturations compared to standard digit pulse oximetry. In this study, Tokuda and coworkers compare the response times to changing SaO_2 of a Masimo LNOP digit sensor, a Nellcor MaxFast forehead sensor and a Masimo TC-1 ear sensor in healthy subjects during breath-holding while in three body positions; head-down, supine and head-up.

Methods

Eight healthy volunteers each wore a Nellcor MaxFast forehead sensor with headband, a Masimo TC-1 ear sensor and a Masimo LNOP digit sensor, connected to the appropriate pulse oximeters and a computer to record data every second. To test the response time to desaturation and resaturation of each pulse oximeter and sensor pair, subjects were instructed to take a deep breath then hold it for as long as possible while in head-up, head-down and supine positions. Recorded data was then analyzed with a Kruskal-Wallis or Wilcoxon Signed Ranks test, as appropriate.

Results

Observed SpO_2 and time for desaturation and resaturation in three positions

Position	SpO_2 Site	Time for desaturation (sec)	Time for start of resaturation (sec)
Head-down	Finger	122.4 ± 42.6	17.2 ± 6.2
	Forehead	111.9 ± 43.4 †	9.6 ± 3.2 ‡
	Ear	112.6 ± 41.1 ‡	10.5 ± 2.2 ‡
Supine	Finger	137.9 ± 51.3	18.8 ± 4.2
	Forehead	134.7 ± 49.2	10.3 ± 2.5 ‡
	Ear	131.0 ± 51.3 †	10.5 ± 2.1 ‡
Head-up	Finger	142.6 ± 46.2	19.5 ± 5.0
	Forehead	136.4 ± 44.9	10.6 ± 3.3 ‡
	Ear	133.8 ± 47.2 †	9.7 ± 3.3 ‡

Data are expressed as mean ± SD. * $P < 0.05$ compared with each other. † $P < 0.05$ and ‡ $P < 0.01$, compared with the finger SpO_2 at each position. Time for desaturation is the interval from the beginning of breath-holding to SpO_2 declining below 90%. Time for resaturation is the interval from the end of breath holding to SpO_2 exceeding minimum value.

While in the head-down position, the ear and forehead sensors detected desaturations significantly faster than the digit sensor. In the supine and head-up position, the ear sensor but not the forehead sensor was significantly faster than the finger sensor. For detecting the time until recovery, both the ear and forehead sensor were significantly faster than the digit sensor.

Conclusions

Forehead reflectance oximetry has been marketed as being faster to changes in oxygen saturation and not prone to the effects of low peripheral perfusion compared to digit transmission pulse oximetry, but its accuracy can to be significantly impaired by venous pooling in supine patients. The ear lobe is a central site where transmission oximetry can be used, thus avoiding low perfusion problems that can affect oximetry from the finger or toe and the accuracy problems that plague forehead reflectance oximetry. This study shows that the Masimo ear sensor is as fast or faster than the Nellcor forehead sensor in detecting desaturations and resaturations in healthy subjects.

14 Avoiding Hyperoxemia During Neonatal Resuscitation: Time to Response to Different SpO_2 Monitors.

Baquero H, Alviz R, Sola A. Presented at the Eastern Society for Pediatric Research Annual Meeting, Philadelphia, PA 2007. Available at https://www.apsspr.org/ESPR/2007_ESPR_Program_Guide.pdf

Introduction

One to two percent of all births require aggressive therapeutic interventions such as neonatal resuscitation.[1] Neonatal resuscitation can lead to hyperoxemia and oxidative stress if excessive inspired oxygen (F_iO_2) is given however, so close monitoring of oxygen saturation values of these patients is necessary to avoid high SaO_2 values. Neonates are prone to exhibit motion and have low perfusion, both of which affect the accuracy and ability to obtain readings with most pulse oximeter technologies. In this study, the investigators tested the time it took for three different pulse oximeter technologies, the Masimo SET Radical, the Nellcor N-395 and the Ohmeda Biox 3700, to obtain stable oxygen saturation readings in newborn infants receiving resuscitation.

Methods

Nineteen newborns from the delivery room and five from the NICU, who required resuscitation, were used for the study. During each resuscitation, two sensors for two different pulse oximeter technologies were applied to the feet or left palm or wrist of the patient. There were 24 resuscitation events during the study. The pulse oximeters used were the Masimo SET Radical with an LNOP Neonatal sensor (n = 24), the Nellcor N-395 with the Oximax-N sensor, (n = 9) and the Ohmeda Biox 3700 with disposable neonatal sensor, (n = 15). The time for each pulse oximeter to reach a stable reading was measured with a digital stop watch and recorded.

Results: Time to Obtain a Stable SpO_2 Reading During Resusciatation

	Mean +/- std (sec)	Median (sec)	Range (sec)
Masimo Radical (n =24)	21.7 +/-7	21	18 - 32
Nellcor N-395 (n = 9)	67.3 +/- 13	71	40 - 89
Ohmeda 3700 (n = 15)	74.2 +/- 12	76	40 - 98

Discussion and Authors' Conclusions:

A fast and accurate SpO_2 reading during newborn resuscitation is essential because even brief exposure to excessive oxygen may result in damage to the immature lung. This study shows that the Masimo SET Radical pulse oximeter was significantly faster at obtaining stable oxygen saturation readings during infant resuscitations compared to the other two other pulse oximetry technologies. The authors of this study conclude: "Adequate and clinically useful reading of SpO_2 is possible during newborn resuscitation. The time to stable and adequate reading is significantly different between SpO_2 monitors. The SpO_2 monitor with the fastest response time would allow for more rapid adjustments of F_iO_2 during resuscitation and avoid unnecessary exposure to hyperoxia".

1. Leone TA, Finer NN. Neonatal Resuscitation: Beyond the Basics. Neo Reviews 2005; 6(4):e177-83.

15 Accuracy of a Novel Bioacoustic Sensor in Adult Postoperative Patients with and without Lung Disease.

Macknet M, Kimball-Jones P, Applegate R, Martin R, Allard M. *Anesth Analg.* Accepted. In press.

Respiration monitoring is an important safety measure for spontaneously breathing patients in the operating room, post anesthesia care unit (PACU) and general care ward. Current methods for monitoring respiration include cannula systems, which can become occluded or dislodged and impedance pneumography which is prone to missing obstructive apneas. Macknet and coworkers from Loma Linda University Department of Anesthesiology, evaluated the accuracy of a new bioacoustic sensor from Masimo Corporation, in adult PACU patients with and without lung disease which is designed to continuously and noninvasively monitor patient respiration.

Methods

Nineteen adult, PACU patients without chronic obstructive pulmonary disease (COPD), (mean age 54.6 +/-20.7 years) and 11 PACU patients with COPD (mean age 51.1 +/- 9.8 years), were monitored with a nasal cannula connected to a BCI capnometer (SIMS, Waukesha, WI) and an adhesive bioacoustic sensor attached to the neck area and connected to an acoustic respiration monitor prototype (Masimo Corp, Irvine CA). Both the capnometer and the bioacoustic monitor from each patient were connected to computers for continuous data recording and analysis. Accuracy, bias and precision were calculated by comparing data from both the bioacoustic sensor and capnometer to a reference respiratory rate from a manual scoring system. Respiratory rate varied 3 to 28 bpm in the patients during the monitoring time which was 58.2 +/- 36.9 min.

Results

	Bias	Precision	% ARMS
Capnography vs Reference Value in Patients without COPD (n=11)	-0.48	2.20	2.25
Masimo Bioacoustic Sensor vs. Reference Value in Patients without COPD (n=11)	0.04	2.43	2.43
Capnography vs Reference Value in Patients with COPD (n=19)	-0.31	2.46	2.48
Masimo Bioacoustic Sensor vs. Reference Value in Patients with COPD (n=19)	0.01	2.76	2.76

Author's Conclusion

"This data suggests the new bioacoustic sensor may provide a system at least as accurate as capnography for monitoring respiration in spontaneously breathing patients with and without COPD. This device offers multiple benefits over existing devices and has a potential to improve monitoring of both healthy patients and patients with lung disease in a general care setting."

16 Clinical Practice and SpO_2 Technology in the Prevention of ROP in VLBW Infants.

Castillo AR, Deulofeut R, Sola A. Presented at the Pediatric Academic Societies Annual Meeting. May 5-8, 2007. Toronto Canada. Available at http://www.abstracts2view.com/pas/search.

Introduction

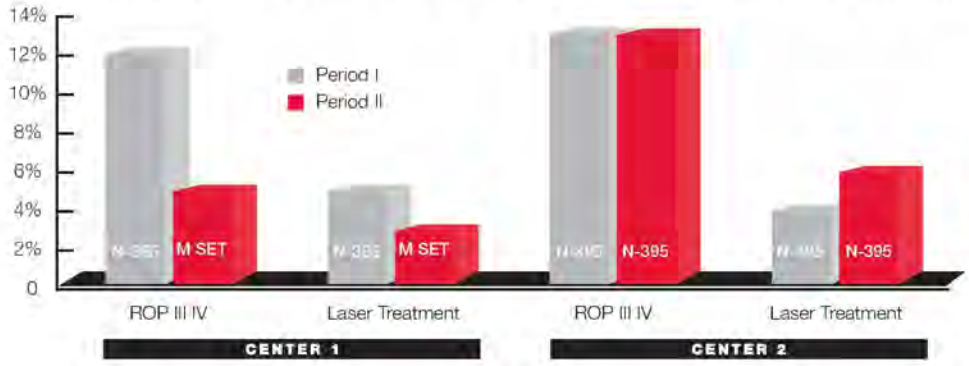
Strict management of O_2 delivery in very low birth weight (VLBW) infants has been associated with decreased rates of Retinopathy of Prematurity (ROP), a devastating disease that can result in lifetime blindness. Because the accurate monitoring of oxygen saturation in these patients is an essential part of the clinical practice change which is thought to decrease the incidence of ROP, these researchers tested whether the performance of the pulse oximeter used was associated with a reduction in the rate of ROP.

Methods

To compare the incidence of severe ROP (ROP III-IV) and laser treatment at two centers using the same treatment protocol but different pulse oximetry technologies, the incidence of ROP was calculated for 449 VLBW infants (<1,250 gm) from two treatment centers during two time periods. Birth weight and gestational age of the patients from both centers were similar (895 +/- 190 gm; 27 +/- 2 days). During Period I (2000-2002) both treatment centers used Nellcor N-395 pulse oximeters to maintain O_2 saturation levels at >95%. During Period II (2003-2004) Center 1 changed to using Masimo SET Radical pulse oximeters and Center 2 continued to use the Nellcor devices (N-395) to maintain O_2 saturation levels at 88-93%. Eye exams for all patients were performed by the same ophthalmology department using the same criteria.

Results

Incidence of ROP II-IV and Laser Treatement when using Nellcor N-395 or Masimo SET Pusle Oximetry



There was a relative risk reduction of 58% for the incidence of ROP III-IV and 40% for the incidence laser treatment following Period 2, with the use of Masimo SET pulse oximetry. There was no significant change in the incidence of these measures following Period 2 with the use of Nellcor pulse oximetry ($p>0.05$).

Conclusion and Authors' comments

Changing to Masimo SET pulse oximetry as part of the overall clinical practice change was associated with a decreased incidence of severe ROP and the need for laser treatment during the period when SpO_2 levels were maintained at 88-93%, whereas no decrease in the incidence of ROP occurred during that period at the center that continued to use the Nellcor pulse oximeters. The authors concluded "Retinopathy of prematurity (ROP) can be a devastating disease. Efforts to lower ROP rates include... guidelines to decrease hyperoxemic periods and wide changes in oxygenation and the advances in SpO_2 technology...In a large group of examined inborn infants ...treated by the same neonatologists, MD's and NNP's, using the same clinical guidelines to decrease hyperoxemia and wide changes in oxygenation, the relative risk reduction of severe ROP and laser therapy are associated with SpO_2 technology utilized. This further supports the significance of adequate SpO_2 monitors in managing critically ill infants."

21 Continuous Noninvasive Measurement of Hemoglobin via Pulse CO-Oximetry During Liver Transplantation, a Case Report

Macknet MR, Kimball-Jones P, Applegate R, Martin R, Allard M. Presented at the 17th Annual Meeting for the Society for Technology in Anesthesia. Available at http:// www.anesthech.org/publications_abstracts.htm#STA2007.

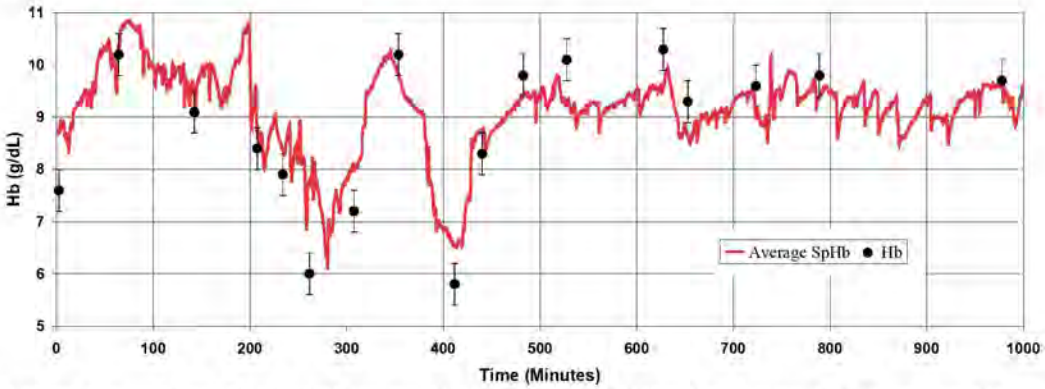
Introduction

This case report examines the ability of a Masimo engineering prototype to continuously and noninvasively measure total hemoglobin concentration (SpHb) during liver and kidney transplantation surgery.

Methods

A 65 year old female scheduled to undergo liver and kidney transplantation was monitored with three prototype SpHb sensors, optically isolated from each other and attached to a data collection system. The patient was monitored throughout the course of the surgery, for a total of 16.6 hours, during which 17 Hb/SpHb data pairs were collected. Arterial blood samples were collected every hour or more frequently if clinically indicated. Arterial blood samples were analyzed by a laboratory CO-Oximeter, the readings of which were statistically compared to the corresponding SpHb readings. Range, bias and precision were calculated from the average reading of the three SpHb sensors at each time point compared to the laboratory CO-Oximeter readings.

Results



Total hemoglobin ranged from 5.8 to 10.3 g/dl. The bias of the SpHb sensors was 0.146 and precision was 0.740. The precision of the CO-Oximeter was 0.4 g/dL

Authors' Conclusions

"SpHb correlated well with CO-Oximeter determined Hb during most of this complicated procedure. Measurements showed good correlation during times of rapidly changing Hb concentration related to surgical blood loss and transfusion. Continuous and noninvasive hemoglobin monitoring would be an extremely useful tool in many clinical scenarios. This technology has the potential to greatly improve patient care and safety during surgical procedures."

24 Pulse Oxymeter Perfusion Index as a Predictor for the Effect of Pediatric Epidural Block

Uemura A, Yagihara M, Miyabe M. *Anesthesiology* 2006; 105: A1354.

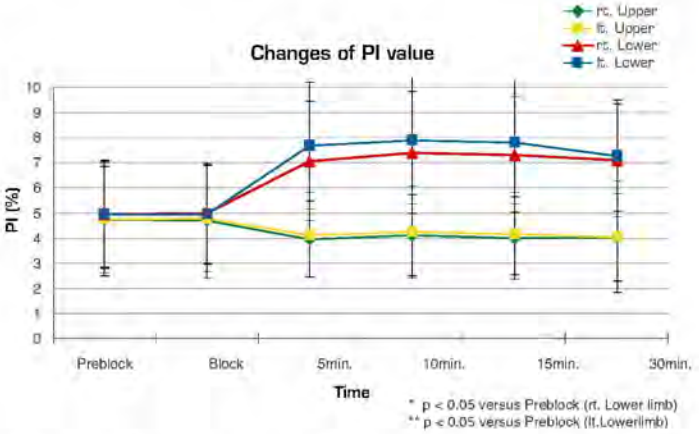
Introduction

Epidural block is a common method of pain management during surgery. It can be difficult to non-invasively evaluate the success of the block, however, especially in pediatric patients. In this study, Uemura and coworkers assessed a method for predicting the effectiveness of an epidural block in pediatric patients by the use of perfusion index (PI), a feature available on the Masimo SET pulse oximeter.

Methods

Fifty children who were scheduled to receive inguinal herniorrhaphy surgery were monitored with four Masimo SET Radical pulse oximeters, one on each limb. PI was recorded with PhysioLog® (Masimo Corp) for later analysis. Non-invasive blood pressure, heart rate, endtidal CO_2, endtidal Sevo%, respiratory rate and ECG were also recorded during the procedure. Anesthesia was induced with nitrous oxide-oxygen-sevoflurane via mask. Forty of the patients received a one shot lumbar epidural block with 0.2% ropivacaine (0.7ml/kg). Epidural space (L2/3) was identified with the drip infusion method. The ten patients who did not receive the epidural block were administered acetaminophen via suppository.

Results



Four minutes after receiving the one shot lumbar epidural injection, the average PI values of both lower limbs of the patients were significantly increased compared to both upper limbs ($P<0.05$). The patients that had symptoms of a failed epidural block (elevated heart rate, respiratory rate and movement after incision) showed a lower average PI of the lower limbs. The ten patients that did not receive the epidural block showed a low average PI in all limbs.

Author's Conclusions

"The pulse oximeter PI reflects the peripheral perfusion and is changed by epidural block; [therefore] PI value can be used as a prediction for the effect of epidural block. As we use pulse oximetry routinely in every patient during operations, PI value is useful, objective, and non-invasive method to evaluate the effect of epidural block in pediatric patients."

29 Comparison of Three New Generation Pulse Oximeters during Motion & Low Perfusion in Volunteers

Shan N, Estanol L. *Anesthesiology* 2006; 105: A929.

Introduction

Many pulse oximeter (PO) technologies claim to give accurate readings during conditions of patient motion and low perfusion. Accurate and reliable pulse oximetry monitoring is an increasingly essential clinical tool throughout the hospital with the trend of moving patients earlier from the ICU onto the general care floor. In order to determine which of three new generation pulse oximetry technologies provide the most reliable and accurate readings during difficult patient conditions, these researchers compared the specificity (ability to reject false alarms) and sensitivity (ability to detect true alarms) of the Masimo Radical, the Nellcor N-600 and the Datex Ohmeda TruSat on healthy volunteers during periods of normoxia and hypoxia during motion and induced low perfusion.

Methods

To test the performance of three pulse oximetry technologies; the Masimo Radical (V5.0), the Nellcor N-600 (V1.1.2.0) and the Datex Ohmeda TruSat) optically shielded sensors were randomly placed on index, middle, and ring fingers of left hand (test), and right hand (control) of 10 healthy volunteers Low peripheral perfusion was induced by lowering the room temperature to 16-18°C. The motions were random self generated (SG) and machine generated (MG) with the test hand attached to a motion table. A rebreathing circuit with a CO_2 absorber was used to induce desaturation to approximately 75%. The subject was then given 100% O_2 until the control pulse oximeters reached a SpO_2 of 100%. The sensors were rotated laterally and tested on all three fingers during the room air events. A computer recorded SpO_2 and pulse rate (PR) data. A missed event was defined as the inability of the PO to detect desaturation and/or recover from a desaturation by the time the control reached 100%. A false alarm was recorded during the normoxic phase, and defined as a $SpO_2 \leq 90\%$ during motion. ANOVA, with a Fischer's post hoc test, and Chi-square analysis, as appropriate, were used to compare the sensitivity and specificity for the three oximeters. A $p < 0.05$ was considered statistically significant.

Results

One hundred and sixty (160) motion tests were performed; 120 on room air and 40 during desaturation. Missed events (sensitivity) were counted for the desaturation episodes (20 with MG and 20 with SG). False alarms were counted for the 120 room air motions (60 with MG and 60 with SG). The results are shown in the table below.

Machine and Self Generated Motion

Device		Missed Event	Sensitivity	False Alarm	Specificity
Masimo SET Radical (v5.0)	*MG*	0/20	100	4/60	93
	SG	1/20	95	2/60	97
Nellcor N-600 (v1.1.2.0)	*MG*	7/20	65*	20/60	67*
	SG	10/20	50*	14/60	77*
Datex-Ohmeda TruSat	*MG*	16/20	20*	10/60	83*
	SG	17/20	15*	11/60	82*

$p < 0.05$ compared to Masimo

Authors' Conclusions

"During hypoxic/normoxic and low perfusion states, Nellcor N-600 (v1.1.2.0) and Datex Ohmeda TruSat performed inferior to Masimo Radical (v5.0) with respect to maintaining accurate readings during both machine generated and self generated motions. It appears from this study that Masimo Radical may work better for patient safety, especially at critical times in OR, PACU, and ICU."

33 Measurement of Carboxyhemoglobin and Methemoglobin by Pulse Oximetry; A Human Volunteer Study

Barker SJ, Curry J, Redford D, Morgan S. *Anesthesiology* 2006; 105(5): 892-897

Introduction

Until recently, all pulse oximeters on the market used two wavelengths of light to estimate arterial hemoglobin saturation. These two-wave length technologies do not have the capability to distinguish dyshemoglobins from oxygenated hemoglobin resulting in erroneous SpO_2 readings when dyshemoglobins are present in the blood. Masimo Corporation has developed a new, 8-wavelength Pulse CO-Oximetry platform, Masimo Rainbow SET, which is designed to measure carboxyhemoglobin (SpCO) and methemoglobin (SpMet) as well as traditional SpO_2 values. This study tests the accuracy and reliability of Masimo Rainbow SET Pulse CO-Oximetry in measuring these dyshemoglobins in human volunteers.

Methods

Twenty healthy volunteers (two groups of 10) were fitted with peripheral venous and radial arterial cannuli and monitored by a three-lead electrocardiograph and automated sphygmomanometer. Each subject also wore six Masimo Rainbow sensors (on digits 2, 3 and 4 of both hands), each connected to a different Rainbow SET Pulse CO-Oximeter.

Carboxyhemoglobin Group

The ten subjects of the carboxyhemoglobin group wore a tight fitting breathing mask connected to an anesthesia machine for the delivery of a controlled mixture of air and CO. After obtaining baseline values, subjects breathed approximately 500 ppm of CO until they reached a maximum COHb level of 15%, at which point the F_iO_2 was changed to 100% until subjects reached a COHb level of 10%, then the mask was removed and they breathed room air. During baseline, CO administration and recovery, blood samples were taken every 10 minutes, via the radial artery cannula, for analysis by laboratory CO-Oximetry. Data was pooled for the 10 subjects to determine bias, precision, linear regression and the correlation coefficient for the data collected from the Rainbow SET Pulse CO-Oximeter compared to the average of the readings from three laboratory CO-Oximeters.

Methemoglobin Group

The ten subjects of the methemoglobin group were given an intravenous infusion of sodium nitrite at a rate of 6 mg/min to a total dose of 300 mg to induce methemoglobinemia. Prior to nitrite administration, during treatment and during recovery, blood samples were taken every 10 minutes, via the radial artery cannula, for analysis by laboratory CO-Oximetry. Recovery phase lasted until the methemoglobin level of each subject had decreased by at least 5% from its peak value. Data was pooled for the 10 subjects to determine bias, precision, linear regression and the correlation coefficient for the data collected from the Rainbow SET Pulse CO-Oximeter compared to the average of the readings from three laboratory CO-Oximeters.

Results

Figure 1.

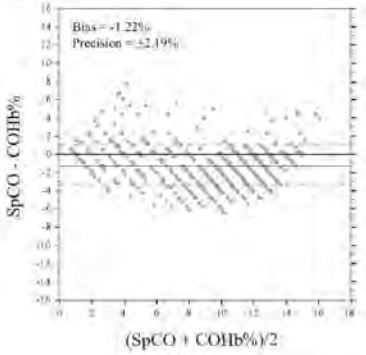


Figure 2.

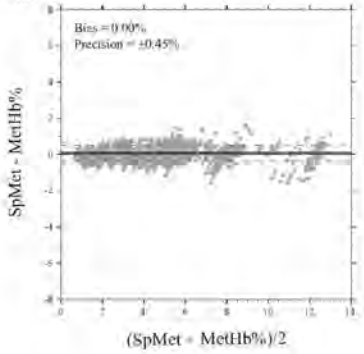


Fig 1. Bias plot of (SpCO - COHb%) verses (SpCO + COHb%) / 2
Pooled data for 10 subjects. SpCO is the Rainbow Pulse CO-Oximetry measurement of carboxyhemoglobin; COHb% is the average of three laboratory CO-Oximeters' measurements of carboxyhemoglobin. Lines show values of bias (solid) +/- precision (long/short dash).

Fig 2. Bias plot of (SpMet - MetHb%) versus (SpMet + MetHb%)/2
Pooled data for 10 subjects. SpMet is the Rainbow Pulse CO-Oximetry measurement of methemoglobin; MetHb% is the average of three laboratory CO-Oximeters' measurements of methemoglobin. Lines show values of bias (solid) +/- precision (long/short dash).

The pooled data for the ten subjects of the carboxyhemoglobin group show that Rainbow Pulse CO-Oximetry has a bias of -1.22 and a precision of 2.19 for SpCO, when compared to the average COHb reading from a laboratory CO-Oximeters. The Rainbow Pulse CO-Oximetry had a bias of 0 and a precision of 0.45 when calculated from the pooled SpMet readings, compared to the average MetHb reading collected from a laboratory CO-Oximeter. The precision of Rainbow Pulse CO-Oximetry SpCO measurement is about the same as that specified for conventional pulse oximeters. The precision of Rainbow Pulse CO-Oximetry SpMet measurement is approximately the same as a laboratory CO-Oximeter, when used within the ranges covered by this study.

Discussion

Carbon monoxide poisoning is the most common type of fatal poisoning in the United States with at least 5,000 fatalities and accounting for 49,000 ER visits annually in the U.S. alone. Methemoglobinemia, another potentially fatal dyshemoglobin disorder, can be caused by the use of commonly prescribed drugs like dapsone, benzocaine and other "caine" sprays as well as dehydration, sepsis, or accidental ingestion or inhalation of industrial chemicals. A retrospective study conducted at Johns Hopkins Bayview Medical Center found 138 cases of acquired methemoglobinemia over a 28 month period, including one fatality and three near fatalities[1]. Despite the high incidence of these two dyshemoglobin disorders, methods for measuring COHb and MetHb have been limited to time and labor consuming invasive blood tests done in hospitals and laboratories with laboratory CO-Oximeters. However, less than half the hospitals in the US have the capability to measure COHb and MetHb via laboratory analysis.[2] Masimo Rainbow SET Pulse CO-Oximetry provides an inexpensive and easily integrated method for solving this serious public health deficiency.

Authors' Conclusions

"Masimo Rainbow SET [Pulse CO-Oximetry] seems to be a major advance …We have found it to be capable of detecting and measuring both methemoglobin and carboxyhemoglobin. It represents a significant improvement in our oxygenation monitoring capability."

1 Ash-Bernal R, Wise R, Wright S. Acquired Methemoglobinemia. A Retrospective Series of 138 Cases at 2 Teaching Hospitals. Medicine. 2004; 83:265-273.

2 Hampson, N. Carboxyhemoglobin Measurement by Hospitals: Implications for the Diagnosis of Carbon Monoxide Poisoning. Journal of Emergency Medicine. 2006 Jul; 31(1): 13-6.

37 Noninvasive Carboxyhemoglobin Monitoring: Screening Emergency Department Patients for Carbon Monoxide Exposure

Partridge R, Chee KJ, Suner S, Sucov A, Jay GD. *Respiratory Care*. 2006; 51(11); 1332.

Introduction

Symptoms of carbon monoxide toxicity (COT) are variable and non-specific and so are often confused with the symptoms of other common illnesses like flu. It is likely, therefore, that many cases of COT go undiagnosed by healthcare professionals, even though it is the most common type of accidental poisoning in the United States. The researchers utilized a new monitor, the Masimo SET Rainbow Rad-57 Pulse CO-Oximeter, to noninvasively measure carboxyhemoglobin in the blood of all ER admissions at their hospital, to determine the prevalence of unexpected cases of COT.

Methods

Pulse oximeters in the Emergency Department (ED) of an urban, academic hospital (with 95,000 annual visits) were replaced with Masimo SET Rainbow Rad-57 Pulse CO-Oximeters, prior to a retrospective chart review. Nurses were instructed to use the Rad-57 Pulse CO-Oximeter to noninvasively measure the carboxyhemoglobin levels (SpCO) of all adult patients presenting to the ER over a 3-month period, in order to determine if unsuspected cases of COT could be detected.

Results

Over the three-month period, over 10,000 emergency room patients were monitored for carboxyhemoglobin as part of the intake procedure. Nine of these patients, who presented with non-specific symptoms or unrelated complaints, were found to have toxic COHb levels with the Masimo Rad-57 Pulse CO-Oximeter. The toxic levels ranged from 16-33% and were confirmed with blood gas analysis. The sources of the CO exposures in the patients with COT were later identified and were usually in the home. Additionally, all patients with presumed toxic COHb levels due to smoke inhalation were identified with the Masimo Rad-57. Thirteen patients had false positive SpCO values with the Masimo Rad-57 (based on laboratory CO-Oximetry), but no false negatives were observed.

Conclusions

If the rate of unexpected CO poisonings found in this study was indicative of all US hospitals, it would equate to as many as 50,000 cases of unsuspected CO toxicity annually, nationwide. In this study, the Masimo SET Rainbow Rad-57 Pulse CO-Oximeter provided an easy and effective means of identifying both suspected and unexpected cases of COT as part of the ED patient admissions process. According to the authors of this study, "noninvasive testing for COT can be performed at ED triage…Unsuspected COT may be identified using noninvasive COHb screening and the prevalence of COT may be higher than previously recognized."

48

A Comparison of the Accuracy of Three New Generation Pulse Oximeters (POs) During Motion and Low Perfusion in Human Volunteers

Shah N, Taleghani A, Chitkara A, Miller JM. *Anesthesiology* 2005;103:A1168.

Introduction

Pulse oximetry can be evaluated in terms of "sensitivity" and "specificity," where sensitivity is defined as the ability to detect true alarm events, and specificity is defined as the ability to resist false alarms. Using adult volunteers, these researchers tested the Masimo SET Radical, Philips CMS, and Nonin 9700 pulse oximeters during normoxia and laboratory-induced hypoxia combined with machine generated (MG) or subject generated (SG) motion.

Methods

189 motion tests during normoxia and hypoxia were performed on 9 adult volunteers. The testing room was initially cooled to 16-18 degrees Celsius to reduce peripheral perfusion. Volunteers were then outfitted with optically shielded, randomly placed finger sensors, which were then placed on a motor-driven random motion table, subjecting the hand to induced rubbing and tapping motions. A Masimo ear sensor was used as a control during the hypoxia studies. Hypoxia was induced using a re-breathing circuit with a CO_2 absorber to reach approximately 75% SpO_2 (ear). The subject was then given 100% O_2 until the control pulse oximeters reached 100%. Motion tests were run both using the motion table and using subject generated motions. Data for motion table and self-driven motion were recorded separately. Data was recorded during normoxic and hypoxic conditions. False alarms were noted when SpO_2 dropped below 90% during normoxic conditions. A missed event was defined as the inability of the monitor to recover after the desaturation, by the time the control monitor reached 100%.

Results

Missed events (desaturation/resaturation) were counted for the 54 motion events during hypoxia (36 with MG and 18 with SG) and false alarms were counted for the 135 room air motions (81 with MG and 54 with SG). As seen in the table below, the Masimo SET Radical has significantly higher sensitivity and specificity than either the Philips CMS (rev C1) or the Nonin 9700 (2004) pulse oximeters.

Sensitivity and Specificity of Pulse Oximeters during Motion

Pulse Oximeter		Missed Event	Sensitivity	False Alarm	Specificity
Masimo SET Radical (v4.3)	MG	1/36	97%	1/81	99%
	SG	0/18	100%	0/54	100%
Philips CMS (rev C1)	MG	6/36	83%*	3/81	96%*
	SG	2/18	89%*	4/54	93%*
Nonin 9700 (2004)	MG	13/36	64%*	7/81	86%*
	SG	9/18	50%*	11/54	80%*

*p=<0.05 vs. Masimo Radical

Authors' Discussion and Conclusions

"During hypoxic and low perfusion states, Masimo Radical PO (v4.3) outperformed Philips CMS (rev C1) and Nonin 9700 (2004) with respect to maintaining accurate readings during motion. Thus Masimo Radical may provide better patient safety by more accurate monitoring of SpO_2 and PR."

50 Clinical Evaluation of the Accuracy of Masimo SET and Nellcor N-595 Oximeters in Children with Cyanotic Congenital Heart Disease

Whitney GM, Tucker LR, Hall SR, Chang AC. *Anesthesiology* 2005;103:A1344.

Introduction

Masimo has developed a unique pulse oximetry sensor – the Masimo SET LNOP Blue Sensor - specifically for children with cyanotic congenital heart disease. This patient population, due to their chronically poor peripheral perfusion and low oxygen saturation, has long suffered from pulse oximetry inaccuracy. These researchers tested the new Blue sensor, used with the Masimo SET Radical pulse oximeter, by running side-by-side performance tests against the Nellcor Oximax Max-I sensor, Nellcor's standard sensor for children 3 – 20 kg.

Methods

Seven cyanotic congenital heart disease patients with SaO_2 < 90% were enrolled and continuously monitored with the Nellcor Oximax Max-I sensor connected to the Nellcor N-595 pulse oximeter and the Masimo SET LNOP Blue Sensor connected to the Masimo SET Radical pulse oximeter. The sensors were used on sites recommended by the manufacturers. Pulse oximetry measurements were analyzed and compared to periodic measurements of SaO_2 of whole blood.

Results

A total of 22 SaO_2 measurements were recorded. The mean SaO_2 was 75.8% ± 9.3% (60.9% - 91.0%). There was a significant difference in bias (SaO_2 – SpO_2) and precision (± 1 SD) between the sensors detected in patients with cyanotic congential heart disease (p = 0.0001). See the table below.

Bias and Precision of Masimo SET Radical with LNOP Blue Sensor vs. Nellcor N-595 with Max-I sensor

	Bias (SaO_2 – SpO_2)	Precision (+/- 1 SD)
Radical with Blue sensor	0.17	2.51
Nellcor N-595 with Max-I sensor	5.63	5.24

Authors' Conclusions

"Masimo SET Blue Sensor technology offers improved accuracy in the monitoring of SaO_2 when compared to the Nellcor N-595 pulse oximeter in patients with cyanotic congenital heart disease. This represents a significant advance in the care of this complicated group of patients."

51 Masimo SET Technology Using Perfusion Index Is a Sensitive Indicator for Epidural Onset

Kakazu CZ, Chen BJ, Kwan WF. *Anesthesiology* 2005; 103: A576.

Introduction

Perfusion Index (PI) reflects the degree of pulsatile blood flow at the monitoring site. Various factors including vascular tone can influence the PI values. The authors have previously demonstrated that increases in PI values are a rapid and reliable indication of a functioning epidural catheter.[1] The authors conducted this study to determine the sensitivity of the PI value to small test doses of epidural anesthetic. The benefit of this would be that the functionality and placement of the epidural catheter could be determined prior to the infusion of the full anesthetic dose.

Methods

A total of 16 adult women undergoing labor had a Masimo SET Radical attached to the toe prior to epidural catheter placement. Baseline values for blood pressure, heart rate and PI were noted and recorded every minute thereafter. Following this, an epidural catheter was placed and a small test dose of local anesthetic was administered. Five minutes later the epidural catheter was infused with incremental doses of 0.25% bupivicaine.

Results

Paired t-test comparing baseline PI vs 5 min PI, baseline PI vs 20 min PI and 5 min PI vs 20 min PI shown below, demonstrate significant changes in PI over time following infusion of anesthetic test dose. Figure two shows the distribution (with the lowest bar representing the 10th percentile and the upper most bar representing the 90th percentile of the data) of the PI values at each of the time periods; at baseline, 5 minutes, and 20 minutes.

Figure 1

Paired t-test
Hypothesized Difference = 0

	Mean Diff	DF	t-value	p-value
Baseline PI, 5 min PI	-1.845	15	-5.171	.0001

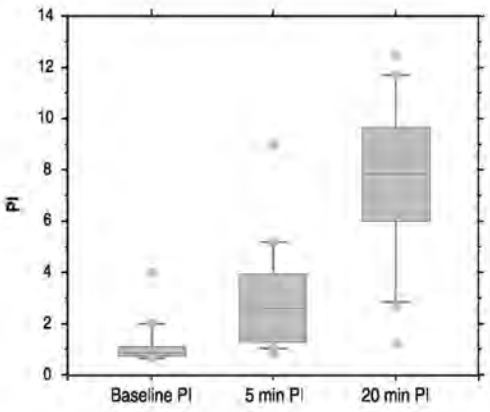
Paired t-test
Hypothesized Difference = 0

	Mean Diff	DF	t-value	p-value
Baseline PI, 20 min PI	-6.269	15	-8.335	<.0001

Paired t-test
Hypothesized Difference = 0

	Mean Diff	DF	t-value	p-value
5 min PI, 20 min PI	-4.424	15	-5.687	<.0001

Figure 2



Discussion

Easy and rapid detection of a functioning epidural catheter is important, especially in the laboring patient. After infusion of a small amount of local anesthetic solution (3ml), the average PI doubled from baseline to 5 minutes.

Authors' Conclusions

"PI is a sensitive indicator of a standard test dose of 1.5% lidocaine with 1:200,000 epinephrine (p-value=0.0001... Early dection of proper catheter placement is paramount in the obstetrical patient. We have devised a sensitive and reliable monitor for early detection of epidural anesthesia onset by measuring tissue perfusion changes in the lower extremities."

1. Kakazu CZ, Wu T, Chen BJ, and Kwan WF; Toe Perfusion Index as an early detection device for Proper Epidural Catheter Placement in Obstetrical Patients. *Anesthesiology* 2004, 101:A-1187.

55

Comparison of the Masimo Rad-57 Pulse Oximeter with SpCO Technology against a Laboratory CO-oximeter Using Arterial Blood

Mottram C, Hanson LJ, Scanlon PD. *Respiratory Care* 2005;50(11):1471.

Introduction

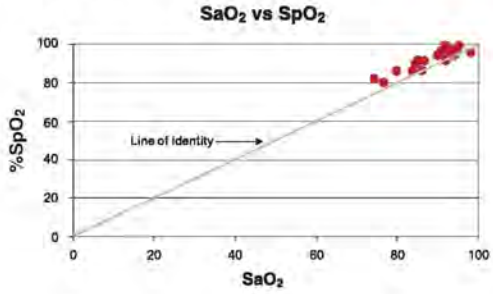
Masimo has developed a new technology called Masimo Rainmbow SET, which measures functional oxyhemoglobin (SpO_2), methemoglobin (SpMet) and carboxyhemoglobin (SpCO). The standard diagnosis and treatment of carbon monoxide poisoning uses invasive and costly blood measurements. These researchers at the Mayo Clinic tested the new Rad-57 Pulse CO-Oximeter for corroboration of the standard arterial blood gas sample analyzed on a laboratory CO-Oximeter.

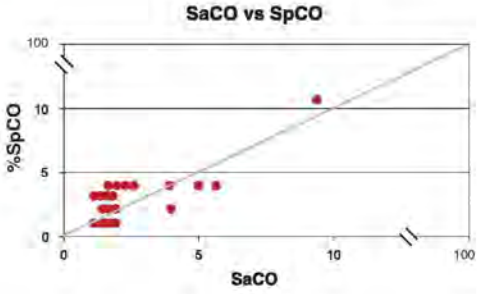
Methods

31 subjects requiring arterial blood gas tests were measured with a Masimo Rainbow SET digit sensor connected to a Rad-57 prior to the drawing of the blood. The SpO_2 and SpCO were recorded during the blood sampling. The blood was analyzed within 15 minutes using a pre-calibrated and quality-controlled Radiometer ABL 725 analyzer according to standard laboratory practice. The data were analyzed using a Student paired t-test.

	SaO_2 (ABG)	SpO_2 (Rad-57)	SaCO (ABG)	SpCO (Rad-57)
Mean	90.8 ± 5.4 SD	93.8 ± 4.2 SD	2.0 ± 1.8 SD	2.5 ± 2.0 SD
Maximum	97.5	99	9.3	11
Minimum	74.6	80	0.8	1
P-value		<0.001		<0.015

Results





Authors' Discussion and Conclusions

"The Masimo Rad-57 pulse oximeter measures functional oxyhemoglobin (SpO_2) ($p<0.001$) and SpCO ($p<0.015$) accurately... the device does appear to identify elevated SaCO and would be helpful in clinical scenarios where non-invasive assessment of SaCO is beneficial. In the subject where SaCO was very significant, subtracting the SpCO value from the function oxyhemoglobin value (SpO_2) would have yielded a SpO_2 that was clinically useful (SpO_2 94% - SpCO 11% = adjusted SpO_2 83%, fractional SaO_2 = 86.7%)."

58 Screening for Duct-Dependent Congenital Heart Disease with Pulse Oximetry: A Critical Evaluation of Strategies to Maximize Sensitivity

Granelli A D, Mellander M, Sunnegardh J, Sandberg K, Ostman-Smith I. *Acta Paediatrica* 2005;94:1590-1596

Introduction

Congenital heart disease (CHD) is relatively common, presenting in 5 to 10 of every 1,000 live births. Early diagnosis and treatment has improved outcomes in this population. Unfortunately, current screening practices still miss a number of infants with CHD who are sent home undiagnosed. Up to 30% of deaths due to CHD in the first year of life are due to unrecognized cases that die in the community. It has been suggested that pulse oximetry might be helpful in detecting infants who may have CHD.[1] This study was designed to find out the sensitivity that could be expected from arterial saturation monitoring by observing the differences in pre and postductal measurement of SpO_2 in a population of healthy infants and a population of infants with CHD. In addition, these researchers studied the differences in the ability to detect CHD (sensitivity) between conventional and new generation pulse oximetry.

Methods

Two hundred (200) healthy newborns and sixty-six (66) infants with CHD were studied. A Masimo SET Radical with LNOP-neo sensor and a convention pulse oximeter, the Datex-Ohmeda TuffSat, with the Flex II sensor were used on each infant. The measurements were carried out in the following manner. One sensor/pulse oximeter combination was placed on the right hand of the infants while the other sensor/pulse oximeter was placed on either foot. Once readings were obtained, the sensors were switched and readings were taken at the other site. The pulse oximeters were randomly placed with each infant.

Results

The Masimo SET Radical obtained readings in all CHD infants, while the Datex-Ohmeda TuffSat obtained readings in only 76%. In addition, many SpO_2 readings less than 95% (false positives) were recorded in the normal group with the Datex-Ohmeda TuffSat. Because of this false positive rate and inability to measure in numerous infants, this conventional pulse oximeter was excluded from further analysis. By defining a positive test for CHD as a SpO_2 of < 95% in the hand and foot or a hand-foot difference of > ±3%, the screening method with the Masimo SET Radical reaches a sensitivity of 98.5%, a specificity of 96.0%, a positive predictive value of 89%, and a negative predictive value of 99.5%.

N=200 CHD Infants	% of Patients Device was Able to Obtain a Reading	Sensitivity for Detecting CHD	Specificity for Detecting CHD
Masimo SET Radical	100%	98.5%	96%
Datex Ohmeda TuffSat	76%	*Not Usable*	*Not Usable*

Authors' Discussion and Conclusions

"This study shows that the sensitivity of screening for critical congenital heart disease with pulse oximetry can be very high if a high-performance new-generation oximeter is used, and if not only postductal saturation but saturation difference between the right hand and one foot is measured."

1. Koppel et al. Effectiveness of Pulse Oximetry Screening for Congenital Heart Disease in Asymptomatic Newborns. *Pediatrics* 2003:111:451-455.

63

Masimo – A New Reliable Non Invasive Method of Detecting Oxygen Saturation in Critically Ill.

Murthy TVSP, Goyal R, Singh VP. *Indian Journal of Anesthesia* 2005; 49 (2): 133-136.

Introduction

Pulse oximetry is a ubiquitous and mandatory tool for the monitoring of oxygenation in the operating room and critical care units. This study evaluates the performance Masimo SET Pulse Oximetry on critical care patients, after another pulse oximetry technology was unable to obtain accurate readings.

Methods

Twenty critical care or operating room patients, (age range from two days to 67 yrs with a mean age of 47.5 yrs), who were being treated for a wide variety of clinical conditions such as head injuries, multi-organ dysfunction, hepatic surgery, heart surgeries and hip replacement were included in the study. Most of the patients had hypotension and exhibited motion during the study due to shivering or transport. Patients were eligible for the study if the attending clinician could not obtain an oxygen saturation reading with an Agilent M3046A M4, FAST SpO_2 pulse oximeter after repositioning the sensor several times. Once the attending physician determined that the Agilent device could not obtain a SpO_2 reading, the Masimo SET pulse oximeter sensor was applied to the patient's finger adjacent to the Agilent probe. When the Masimo SET pulse oximeter gave a SpO_2 reading, an arterial blood sample was drawn for blood gas analysis (ABG). The pulse rate was recorded from the Agilent device and the Masimo SET device for comparison with the pulse rate displayed on the ECG.

Results

SpO_2 Readings

In the 20 patients used in this study, the Masimo SET pulse oximeter obtained SpO_2 readings in all twenty cases. The SpO_2 readings from the Masimo SET were exact or within 1% of the ABG readings in 17 of the 20 cases. In the other three cases, the Masimo SET was within 5% of the ABG readings. The Agilent device gave a zero reading in 6 cases, a low signal in 7 cases, no signal in 3 cases and erroneous saturation readings (more than 10% off compared to the ABG) in 3 cases. One case was not recorded.

Pulse Rate Readings

The Masimo SET obtained accurate pulse rate readings in 19 of 20 cases and was within 2 bmp of the ECG pulse rate in the remaining case. The Agilent device obtained a pulse rate reading in 10 of the 20 cases but only one of these reading was accurate. The other 9 pulse rate readings from the Agilent device were erroneous.

Authors' Conclusions

"Masimo SET pulse oximetry has shown reliable results in patients with hypoperfusion, hypothermia and motion artifacts. It has reduced the false alarms in the intensive therapy units, thereby increasing caregiver efficiency to a large extent. Masimo SET pulse oximetry promises to be the standard of non-invasive monitoring of oxygen saturation in the critically ill in the near future."

67 The Perfusion Index as Measured by a Pulse Oximeter Indicates Pain Stimuli in Anesthetized Volunteers

Hager H, Church S, Mandadi G, Pully D, Kurz A. *Anesthesiology*. 2004;101:A514.

Introduction

The perfusion index (PI) in the Masimo SET pulse oximetry system reflects the strength of a patient's perfusion at the monitored site by calculating the relation between pulsatile and constant absorbed light. Perfusion at the extremities is known to be affected by vasoconstriction and vasodilation as stimulated by temperature, volume, and anesthetics. The researchers examined whether perfusion was also affected by pain stimuli and, if so, whether the PI could serve as a reliable indicator of pain.

Methods

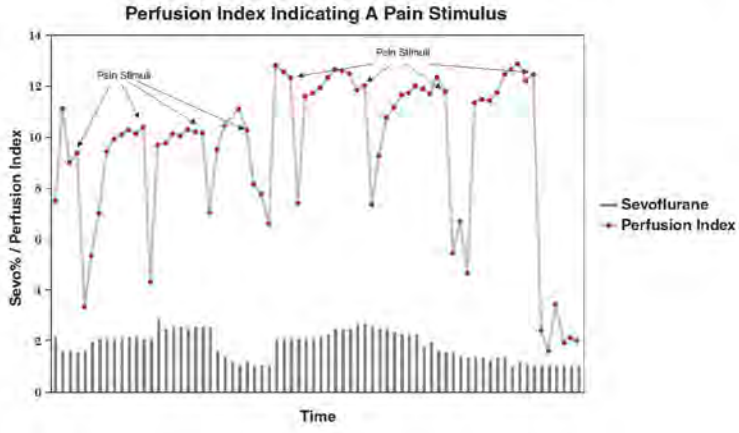
Having obtained informed consent, volunteers were given Propofol (2mg/kg), maintained with Sevoflurane (1.0%, 1.5%, 2.0%, and 2.5% - given in random order), and monitored with ECG, NIBP, and the Masimo SET Radical pulse oximeter. In each condition, standardized painful stimuli were provided by two 25-g electric needles inserted into the lower portion of each subject's anterior thigh. A bilateral 65-70 milliampere, 100 Hz tetanic electrical current was maintained for 10 seconds.

Results

As expected, heart rate and mean arterial blood pressure increased under the influence of painful stimuli, as represented in the table below. The perfusion index followed suit, showing a statistically significant decrease during painful stimuli.

	Heart Rate	Arterial Pressure	Perfusion Index
Pre-Stimulus	62.5 ± 9.5	70.75 ± 9.44	11.07 ± 1.19
During Stimulus	80.38 ± 13.18	92.00 ± 15.11	5.42 ± 2.39
p-value	0.01	0.005	< 0.001

The figure below shows the location of each pain stimulus and the resulting drop in PI.



Authors' Discussion and Conclusions

"The perfusion index is able to independently indicate a pain stimulus in anesthetized volunteers in different concentrations of Sevoflurane. Thus, it may be of clinical value to assess pain."

68 Evaluation of Masimo SET Ear and Forehead Pulse Oximetry and Nellcor MAX-FAST Forehead Pulse Oximetry

Redford D, Lichtenthal P, Barker SJ. *Anesthesiology.* 2004; 101: A593 and A579

Introduction

Most clinical research has found that digit pulse oximetry is typically less subject to the kind of artifact that can compromise a pulse oximeter's ability to faithfully read changing physiology. However, in an effort to achieve faster pulse oximetry response times and access to more stable perfusion, researchers tested sensors designed by Masimo and Nellcor for use on alternative sensor sites - the forehead and the ear. Nellcor manufactures the MAX-FAST forehead sensor for use with the N-595 pulse oximeter. Masimo manufactures the TF-I forehead sensor and the TC-I ("tip-clip") multi-site sensor, for use primarily on the earlobe. Each Masimo sensor is intended for use with the Masimo SET Radical pulse oximeter.

Methods

Following IRB approval, 24 pediatric surgical patients undergoing general anesthesia were monitored with the Nellcor MAX-FAST forehead sensor, the Masimo SET TF-I Forehead Sensor, and the Masimo SET TC-I sensor connected to the earlobe. As controls, the Nellcor Max-P or Max-I connected to the N-595 Pulse Oximeter, and the Masimo LNOP Pdt or Inf-L connected to the Masimo SET Radical were attached to the digits of the test subjects. All pulse oximetry sensors were optically shielded from each other to prevent cross-talk. The mean SpO_2 and pulse rate of the two digit sensors was calculated as the control value. SpO_2 and pulse rate values were recorded from each of the three test sensors and then compared for statistical significance against the control value. Analysis focused on bias (mean error), precision (standard deviation of the E7), E7 (percentage of time during which the SpO_2 reading is outside 7% of the control value in stable conditions), and Performance Index (percentage of time during which the SpO_2 reading is within 7% of the control value).

Results

In 33% of the patients, the MAX-FAST forehead sensor was in error greater than 7% of the control for more than 20% of the surgical procedure. The Masimo sensors both displayed high reliability and accuracy.

	% Bias	% Precision	% E7	Performance Index
Masimo SET TC-I	0.3 ± 0.7	0.5 ± 0.5	0.6 ± 1.5	99.4%
Masimo SET TF-I	0.1 ± 0.5	0.5 ± 0.6	0.6 ± 1.7	99.4%
Nellcor MAX-FAST Forehead Sensor	-4.1 ± 6.0	2.7 ± 3.4	20.2 ± 30.7	79.8%
*p-value (TC-I vs. MAX-FAST)	0.005	0.006	0.004	
*p-value (TF-I vs. MAX-FAST)	0.002	0.006	0.004	

Authors' Discussion and Conclusions

A statistically significant difference was displayed between the Nellcor MAX-FAST forehead sensor and the Masimo SET TC-I and TF-I sensors, with Masimo SET sensors showing much higher accuracy and reliability than the Nellcor MAX-FAST. **The researchers stated, "Because the Nellcor MAX-FAST sensor had significantly longer periods of time [when] SpO_2 reading was falsely low, it is unacceptable for work in the pediatric surgical patient."**

74 Evaluation of the Nares and the Ear as a Site for Oximetry Monitoring in Intraoperative Surgical Patients

Redford DT, Lichenthal P, Barker SJ. *Anesthesia and Analgesia* 2004; 98: S92 and S94

Introduction

The digit is the primary site for pulse oximetry sensors. Due to infrequent periods of low peripheral perfusion or movement, however, alternative sensor sites are sometimes useful. These researchers tested the nares and the ear as alternative sensor sites, using the Masimo TC-I ("Tip Clip") connected to a Masimo SET Radical pulse oximeter.

Methods

Following IRB approval, 17 adult surgical patients undergoing general anesthesia were monitored with five pulse oximeter sensors. A Masimo SET TC-I sensor placed on the ear, a Masimo SET TC-I sensor placed on the nares, and a Nellcor MAX-FAST forehead sensor connected to a Nellcor N595 pulse oximeter served as test sensors. A Masimo SET LNOP Adt sensor placed on a digit and connected to a Masimo SET Radical pulse oximeter and a Nellcor D25 sensor placed on a digit and connected to a Nellcor N200 pulse oximeter served as controls. Data from all oximeters were continuously recorded. The bias (mean error) and precision (standard deviation of the error) of the control (digit) sensors were compared to the mean bias and precision of the forehead, ear and nares sensors. E7 (the amount of time during which the error was greater than 7% in stable conditions) was also analyzed. Error was defined as the difference between the ear or nares sensor and the control sensors.

Results

	% Bias	% Precision	% E7
Control Value (pooled digit data)	-0.1 ± 0.9	0.5 ± 0.4	n/a
Masimo SET TF-I	-0.5 ± 0.7	0.7 ± 0.4	1.0 ± 2.0
Masimo SET TC-I	-0.2 ± 0.7	1.0 ± 1.0	0.7 ± 1.0
Nellcor MAX-FAST Forehead Sensor	-4.0 ± 7.0	3.0 ± 5.0	13 ± 26

Authors Discussion and Conclusions

"Studies from 12 years ago reported that reflectance oximetry sensors performed poorly.[1] Despite advancements in technology, this study demonstrates similar poor performance of the forehead reflectance pulse oximeter. The MAX-FAST sensor attached to the N595 oximeter demonstrated an unacceptable bias and precision and was in error by more than 7% for more than 30% of the total operative time in 18% of patients."

1. *J Clin Monit.* 1991; 7:102-103

82 Comparison of Two New Generation Pulse Oximeters: The Masimo Radical and the Philips Viridia

Goldstein MR, Louie N, Lawas-Alejo P, Pernia ML, Martin GI. *Anesthesiology* 2003; 99:A554
Includes additional information presented in poster format at the American Society of Anesthesiologists 2003 Annual Meeting.

Introduction

"Next generation" pulse oximeters claim motion and low perfusion tolerance. In the NICU, where pulse oximetry has been useful in preventative protocols, as well as, for the detection of life-threatening oxygenation events, the combined effects of low perfusion, motion, and unpredictable interference levels still challenge some pulse oximeters' abilities to accurately and continuously monitor. These researchers tested two next generation pulse oximeters - the Masimo SET Radical v4 and the Philips Viridia Rev C1 - for the performance of each manufacturer's algorithms in detecting and maintaining difficult to read signals.

Methods

Nineteen (19) neonates were studied for a total of 6811 minutes. ECG readings were used to corroborate pulse rate data. Oximeter probes were placed according to manufacturer specification. The criteria for the evaluation were as follows:

1. False desaturation - A reading of <85% saturation with no corroborating physical findings or any corroborating reading from the other pulse oximeter constituted a "false desaturation."
2. Drop Out - An oximeter that gave no SpO_2 and pulse rate reading was considered to have "dropped out."
3. Changes in heart rate - A displayed heart rate differing by more than 25 beats per minute from the value reported by the ECG was considered erroneous.

Results

The Philips Viridia zeroed out and gave no signal for more than 10 times as many instances, and for more than 25 times as long, as the Masimo Radical. There were significant differences in the false desaturations of the two devices, as well as significant differences between the devices in erroneous pulse rate as compared to the ECG. In false desaturations and erroneous pulse rate, the Philips Viridia exceeded the Masimo Radical by greater than twofold instances and threefold duration.

Comparison of the Masimo Radical and the Philips Viridia

	Signal Dropouts (events)	Signal Dropouts (minutes)	Changes in HR>25 BPM (events)	Changes in HR> 25 BPM (minutes)	False Desaturations <85% (events)	False Desaturations <85% (minutes)
Masimo SET®	19	8	7	5	56	15
Philips Viridia C1	194	201	26	11	176	31

*p<0.0001

Authors' Conclusion

"The importance of the evaluation of the device in the at risk population cannot be over-emphasized. Although the newer pulse oximetry technologies are not able to generate a valid pulse oximetry reading in all clinical circumstances, technological advances are not uniform among the different models available. **The Masimo Radical appears to have an advantage in monitoring the at risk neonate.**"

83

Is Pulse Search Technology a Predictor of Unreliable Saturation Monitoring?

Goldstein MR, Louie N, Yang LL, Ochikubo CG, Martin GI. *Anesthesiology* 2003;99:A555.

Introduction

To increase clinical confidence in true alarm situations, such as desaturations, and to reduce the lack of confidence in good data during episodes of patient motion, manufacturers claiming motion tolerant pulse oximetry have attempted to provide easy and continuous assessments of the signal quality of the information used in SpO_2 and pulse rate measurement. The "Pulse Search" warning on the Nellcor N-395 and N-595 oximeters is such a measure. The product manual on the N-395 states, "If the acquired pulse is lost during monitoring, the N-395 enters Pulse Search. During pulse search, the monitor attempts to detect a pulse from which to take a measurement." The Masimo indicator of suspect data is the "Low Signal IQ" message display, which flashes on the screen of the Masimo Radical pulse oximeter when the received signal may be overly compromised. These researchers tested the reliability of the Masimo and Nellcor suspect data indicators.

Methods

The subjects of the test were 19 at-risk neonates. Sensor placement was randomized to one of four extremities and all oximeters were connected to a data collection computer. When a false desaturation to < 85% was noted and confirmed by lack of central cyanosis and presence of normal readings on the other pulse oximeters, presence or absence of the warning indicator (PS or Low SIQ) was recorded. When false desaturation occurred without the presence of a warning indicator, the desaturation was classified as "Unwarned". Conversely, if the false desaturation occurred with the presence of a warning indicator it was classified as "Warned". The duration of the warning indicator was noted and compared to the duration of the associated false desaturation event. Data was compared for statistical significance by ANOVA and a p value of < 0.05 was considered significant.

Results

6,811 minutes of oximetry data were studied. A significant difference in the reliability of the warning indicators to indicate false events occurred (see table).

Comparison of Pulse Search and Low Signal IQ to Warn of False Desaturation Events

	"Warned" # events	Total Time (seconds)	Low SIQ / PS indicator (% total time)	"Unwarned" # events	Total Time (seconds)
Masimo Radical	45	835	96.2	11	65
Nellcor N-595	15	1150	33.0	67	1036
Nellcor N-395	19	510	28.0	37	635

*ANOVA analysis showed a statistically significant difference between the Pulse Search events and duration comparing N-395 / N-595 and the Masimo Radical Low Signal IQ measure for p<0.001.

Authors' Conclusion

"Significant differences in total warned time, duration of warning indicator and unwarned time for detecting false desaturation events are evident between Masimo Radical and the N-395 and N-595 oximeters. The Masimo Radical Low Signal IQ measurement was more reliable in its ability to discern potentially confounding false desaturation."

85 Evaluation of a New Reflectance Forehead Sensor in Detecting Oxygen Desaturation in Patients Undergoing Polysomnography

Whitman RA, Garrison ME, Oestreich TJ, Musumbi MS. *Anesthesiology* 2003;99:A553. Additional information presented in poster format at ASA meeting in San Francisco, October 2003

Introduction

Pulse oximetry provides a critical parameter in the diagnosis and treatment of sleep apnea. This group of researchers has studied Masimo SET pulse oximetry in the past and found it to have better fidelity for Sleep-Disordered Breathing testing as compared to Nellcor pulse oximetry. [1,2] In this study, these researchers wanted to test whether the Nellcor MaxFast forehead sensor, used with the Nellcor OxiMax system improved the performance of the Nellcor system in this clinical environment as compared to the Masimo SET technology.

Methods

Twenty (20) patients undergoing polysomnography were monitored with both MaxFast forehead and Masimo LNOP-Adult digit sensors which were applied according to manufacturer's instructions and connected to the Nellcor N-595 and Masimo Radical pulse oximeters, respectively. The pulse oximeters were turned on simultaneously at the start of the study and turned off simultaneously at the end of the study, and data from the pulse oximeters were downloaded into PROFOX oximetry analysis software. The mean SpO_2, lowest SpO_2, and time with SpO_2 less than 90% were extracted.

Results

In eight (8) of the twenty (20) studies (40%) using the MAXFAST sensor, artifact was clearly identifiable in the graphic output of the saturation profile. This artifact caused erroneous data which was characterized by a sudden shift in saturation that was maintained for a substantial time period not characteristic of desaturation profiles associated with sleep-disordered breathing. No artifact was observed with the Masimo digit sensor. The data pairs were divided into two groups, one comparing the data from the two pulse oximeters for the 8 studies with the MaxFast sensor and having artifact, and the second group with the remaining 12 studies without artifact. (See tables)

Sensor	Mean SpO_2	Lowest SpO_2	Time < 90%
Masimo LNOP-Adt	96.2 ± 2.0 %	83 ± 8%	0.5 ± 1.3%
Nellcor MAX-FAST	94.0 ± 2.6%	73 ± 11%	14.9 ± 17.4%

Group 1. Data from 8 patients with artifact displayed by MaxFast sensor

Sensor	Mean SpO_2	Lowest SpO_2	Time < 90%
Masimo LNOP-Adt	94.6 ± 2.3 %	78± 14%	5.5 ± 12.3%
Nellcor MAX-FAST	94.2 ± 2.7%	82 ± 11%	7.1 ± 15.5%

Group 2. Data from 12 patients with no artifact displayed

Authors' Conclusions

"The Nellcor MAX-FAST reflectance forehead sensor failed to provide accurate SpO_2 data in 40% of the patients undergoing polysomnography. In these cases, the forehead sensor registered a significantly greater percent of time with saturation less than 90%. **The use of this sensor during anesthesia could negatively impact the therapeutic approach in patients with sleep apnea during pre-anesthesia and during post-anesthesia recovery."**

1. Whitman RA. Comparison of the new Masimo SET V3 technology with a conventional pulse oximeter during polysomnography. *Sleep* 2001;24: A412.
2. Whitman RA, Garrison ME, Oestrich PJ. Influence of pulse oximeter technology on hypopnea diagnosis using the newly proposed definition of a respiratory hypopnea. *Sleep* 2002; 25: A509(727.R).

87 Perfusion Index - A Valuable Tool to Assess Changes in Peripheral Perfusion Caused by Servoflurane.

Hager H, Reddy D, Kurz A. *Anesthesiology* 2003; 99: A593.

Introduction

Continuous evaluation of peripheral perfusion during the perioperative period would be useful for the assessment of circulatory status, thermoregulatory responses and the effects of vasoactive agents such as the anesthetic, servoflurane. Skin temperature gradients are a validated measure of fingertip perfusion but this method lacks the sensitivity to detect changes in peripheral perfusion due to some clinical conditions like pain and hypovolemia. Perfusion index (PI), a parameter available on some pulse oximeters, is a measurement of the pulsatile strength at the sensor site and therefore can be an indirect measurement of peripheral perfusion. Hager and coworkers at Washington University compared the sensitivity of Perfusion Index from a Masimo SET pulse oximeter to forearm-fingertip temperature gradient measurements for correlating with endtidal sevoflurane concentration during anesthesia in abdominal surgery patients.

Methods

Seven abdominal surgery patients underwent an anesthesia protocol of propofol and fentanyl followed by sevoflurane and morphine. Forearm-finger tip temperature gradients of each patient were measured with thermacouples taped to the index finger. Perfusion Index was monitored with the Masimo SET pulse oximeter. Data from both devices was recorded 20 minutes after induction of anesthesia to the end of the surgery then analyzed with Pearson's correlation coefficient to determine a linear relationship. 129 paired data points were used for the analysis.

Results

n=129 data points from 7 abdominal surgery patients	Correlation with end-Expiratory Servoflurane (R)
Masimo SET Perfusion Index	0.48, (p<0.001)
Forearm Finger-tip Temperature Gradient	0.05, (p= 0.5)

Perfusion index showed a significant correlation with end expiratory sevoflurane whereas the forearm-finger tip gradient did not. Likewise, perfusion index did not correlate with forearm-finger tip gradients (R= 0.22, p = 0.15).

Authors' Conclusions

"The perfusion index appears to be an accurate tool to assess changes in peripheral perfusion caused by an inhalational agent like servoflurane. It might thus be of future value in assessment of perioperative changes in peripheral perfusion due to different anesthetic conditions."

93 Longevity of Masimo and Nellcor Pulse Oximeter Sensors in the Care of Infants

Erler T, Avenarius S, Wischniewski E, Schmidt K, Kläber H. *Journal of Perinatology* 2003;23:133-135

Introduction

Pulse oximetry is routine for monitoring oxygenation in neonates. If the pulse oximeter sensor is single-patient use and it is short-lived, the cost of monitoring can be high. Since pulse oximetry monitoring of sick newborns is often lengthy, the use of long-lived sensors would benefit the hospital management and lessen patient costs. These physicians (at two hospitals) compared the longevity of the Masimo LNOP Neo and LNOP Neo PT sensors to the Nellcor Oxisensor II N-25 sensors on infants in their Neonatal Intensive Care Units and step-down nurseries.

Methods

121 sick newborns were enrolled in this multicenter study: 56 used Masimo LNOP Neo and LNOP Neo PT sensors and 65 used the Nellcor N-25 sensors. Infants were randomly chosen for monitoring with either the Masimo SET Radical or the Nellcor N-395 and Nellcor N-3000 pulse oximeters. They remained on this monitor/sensor combination throughout the study. The sensors were positioned in an identical fashion and in accordance with the manufacturers' user instructions. The time of sensor placement and replacement were noted along with the reason for changing the sensor. The standard care practices for pulse oximetry were followed, per each institution's use protocol.

Results

A total of 835.5 patient days of monitoring were accumulated on 121 infants. The Masimo Neo sensors had over twice (2.33) the useful life of the Nellcor N-25 sensors (9.05 ± 4.4 versus 3.9 ± 2.3 days, respectively, $p < 0.05$). In addition, the magnitude of the useful life between the two institutions was not significantly different in the Masimo group (2.35 verses 2.22-fold).

	Masimo LNOP Neo	Nellcor N-395 / N-3000 N-25
Sensor life in days (mean ± sd)	9.05 ± 4.4	3.9 ± 2.3

Authors' Discussion and Conclusions

"We are aware that the pricing of the Masimo and Nellcor pulse oximeters is similar, as is the cost of the LNOP Neo and N-25 sensors. Given this, a two-fold increase in sensor life translates into dramatic savings in settings where long-term PO (pulse oximetry) monitoring is routine, such as neonate care."

97 The Use of Pulse Oximetry To Assess the Accuracy of Chest Compressions

Goldstein MR, Furman GI, Lawas-Alejo P, Ochikubo CG, Pernia ML, Sindel BD, Yang LL, Martin, GI. *Pediatric Research* 2003;53(4,2):478A

Introduction

With the rapid improvement of pulse oximetry technology, new applications for the continuous, noninvasive monitoring of arterial oxygen saturation are becoming known. An unintended test of pulse oximetry's ability to monitor the chest compressions of a neonate during resuscitation attempts was performed during a comparative device trial of two next generation pulse oximeters, the Masimo SET Radical v3 and the Tyco-Nellcor N-595.

Case Study Initial Findings

During the comparative device trial, Masimo sensors connected to Masimo Radicals, and Nellcor sensors connected to Nellcor N-595s, were placed on different post-ductal extremities of each infant. An 8-month old, former 26 weeks gestation infant had an episode of severe bronchospasm with desaturation, which led to profound vasovagal stimulation and bradycardia. Both pulse oximeters showed arterial oxygen saturation initially dropping from the 90s to the 30s. Both oximeters also matched the bradycardia as noted on the ECG monitor (<80 bpm). In accordance with AAP resuscitation guidelines, the patient then received handbag ventilation and manual chest compressions.

Case Study Results

During the ensuing 5-minute period of chest compressions, the Masimo SET Radical accurately matched the rate of administered chest compressions and then tracked the pulse rate and oxygen saturation back up to baseline levels as the resuscitation was successfully completed. The N-595 dropped out and gave no readings during the chest compressions. No other resuscitative efforts occurred during study on this or any other patient enrolled in the trial.

Discussion and Authors' Conclusions

Certain next generation pulse oximetry has been shown to effectively contribute to exacting measurement protocols. Resuscitation events, however, have no technology-based standard of care. The motion and low perfusion capabilities of Masimo SET has been shown to provide the high tolerance necessary for implementation of such a protocol. The authors' concluded, "Although the oximetry devices were not used to guide resuscitation, the use in this setting is intriguing. **If the Masimo SET technology can be used to assess the effectiveness of resuscitative efforts, it can dictate a standard of care."**

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Can Changes in Clinical Practice Decrease the Incidence of Severe Retinopathy of Prematurity in Very Low Birth Weight Infants?

Chow LC, Wright KW, Sola A, and the CSMC Oxygen Administration Study Group. *Pediatrics* 2003;111(2):339-345

Introduction

These researchers noted there was a wide variability in the incidence of severe Retinopathy of Prematurity (ROP) in very low birth weight infants reported globally by Neonatal Intensive Care Units (NICUs). They believed, however, that strict management of O_2 delivery and monitoring to minimize episodes of hyperoxia and hypoxia might be associated with decreased rates of ROP. Their objective was to compare the incidence of, and need for surgery for, severe ROP (stages > 3) in infants of 500 to 1500g birth weight before and after implementation of a new clinical practice of O_2 management in their level 3 NICU.

Methods

In April, 1998, the researchers implemented an O_2 management policy. The policy included strict guidelines in the monitoring practices of SpO_2 parameters and of increasing or weaning of oxygen levels in the delivery room, during in-house transport of infants to the NICU and throughout hospitalization. The main objectives were to monitor O_2 levels more precisely and to avoid hyperoxia and repeated episodes of hypoxia-hyperoxia in very low birth weight infants. The policy included selection of equipment for monitoring (Masimo SET), avoidance of repeated increases and decreases of the inspired O_2 (F_iO_2), and modification of previously used alarm limits. Following education on the new protocol, each staff member signed an agreement acknowledging they understood and would adhere to its guidelines. Experienced ophthalmologists, following standard ROP classifications, performed eye examinations on the 447 infants in the study. ROP data from January 1997 to December 2002, for infants of 500 to 1500g, was analyzed.

Results

The incidence of ROP 3 to 4 decreased consistently in the 5-year period from 12.5% in 1997 to 2.5% in 2001. The need for ROP laser treatment decreased from 4.5% in 1997 to 0% in the last 3 years of the study.

Birth Weight	Severe ROP Pre Policy	Severe ROP Post Policy (last 3 years)
500 to 749 g	38%	10 - 12%
750 to 999 g	12 - 15%	0%
1,000 to 1,249 g	12 - 15%	0%

Authors' Discussion and Conclusions

"As part of an organized process of improvement in quality of care, the implementation of a clinical practice change of curtailed O_2 was associated with an important and clinically significant decrease in the incidence of both severe ROP and the need for ROP therapy." During this same period, the global incidence of severe ROP, reported by the Vermont-Oxford Network with data supplied from 400 NICUs, demonstrated no change from the 10 to 12% range. The authors commented further, "We can speculate that the decrease in incidence of ROP was 'gradual' because the change in practice was gradual, as a result of the time that it took for 'buy in' of all bedside nurses and RTs to deliver their practice at all times for all infants. In addition, many of the care providers reported greater ease in following the policy with use of new SpO_2 monitors (Masimo Signal Extraction Technology) with less artifact and false alarms."

103 Use of Pulse Oximetry in Automated O_2 Delivery to Ventilated Infants

Urschitz MS, Von Einem V, Seyfang A, Poets CF. *Anesthesia and Analgesia* 2002;94(S1):S37-40

Introduction

"Oxygen delivery to premature and/or critically ill infants should be closely controlled to achieve adequate tissue oxygenation while minimizing side effects." O_2 therapy usually occurs by manual adjustments against a desired pulse oximeter SpO_2 range. Some pulse oximeters have a history in neonates of alarming falsely, causing many clinicians to set very loose SpO_2 alarm limits. This practice results in overuse of oxygen, which adds cost, patient stay and, more importantly, increases the risks of retinopathy of prematurity and chronic lung disease. The researchers tested an automated system for delivery of oxygen therapy using Masimo SET pulse oximetry as the physiologic endpoint.

Methods

The authors reviewed the history of close-loop O_2 titration in neonates, which has been linked to undesirable change in therapy (largely due to poor pulse oximetry). 126 hours of Masimo SET recordings obtained in 10 preterm infants were used to test their new artificial intelligence controller. The same recordings were used to determine what a clinician would have done given the same pulse oximetry values and condition of the child. All of the controller- and clinician-based adjustments were inspected critically and independently by a NICU nurse and two neonatologists.

Results

The automated, controller-based oxygen therapy changed 148 times (median 1.15/h; range 0.12-2.37), while the clinician-based review made 519 changes (3.83/h; range 1.37-6.50). The 70% reduction in changes/hour was the result of more precise delivery of discrete amounts of oxygen. Additionally, they found their controller-based system was more accurate than older controller techniques, thereby reducing the risk of over and undershooting oxygen delivery.

They also randomly selected 223 desaturations, as measured by Masimo SET, to determine the specificity for a signal quality threshold predictive of false desaturations. 217 of 223 desaturations (97.3%) were determined to be real. Only 6 episodes were found false and all were associated with a Signal IQ < 0.30, the threshold for the Masimo "Low Signal IQ" prompt. The researchers reported that four of the six hypoxemias were missed due to the sensor being off the patient's skin. Signal IQ was further investigated and found to have excellent specificity (75%) and sensitivity (100%). Reading with a Signal IQ < 0.3 were rare (8/233, 3.5%) and confirmed that below this value, the likelihood of artifactual measurements was high (6/8, 75%) whereas above it, erroneous measurements did not occur in their sample. Signal IQ is Masimo's unique signal identification and quality indicator, that helps clinicians identify readings of questionable validity due to extremely challenging motion and low perfusion conditions. "Thus we were able to confirm the validity of using a Signal IQ < 0.3 to warn of potentially unreliable measurement conditions."

Masimo SET®	True	False
Tested Desaturations (n=223)	217	6
"Low Signal IQ" prompt	0	6
Sensitivity of measurement	97.3%	100%

Authors' Discussion and Conclusions

"The new F_iO_2 controller algorithm evaluated in this study appears to lead to a more stable assessment of a patient's oxygenation than previous approaches in this field, probably reducing the risk of false responses resulting from erroneous SpO_2 data. **The latter risk may be further reduced by incorporating information from a signal quality indicator such as Masimo's Signal IQ into this algorithm. This may help to optimize oxygen delivery to premature and/or critically ill infants."**

104 Differences in Pulse Oximetry Technology Can Affect Detection of Sleep Disorders in Children

Brouillette RT, Lavergne J, Leimanis A, Nixon GM, Laden S, McGregor CD. *Anesthesia and Analgesia* 2002;94(S1): S47-53.

Introduction

In spite of the frequency of motion-induced false desaturations, the Nellcor N-200, in its fastest averaging time, had been the preferred pulse oximeter in these researchers' sleep laboratory (The Montreal Children's Hospital). Ultimately, they desired to find a pulse oximeter that would more accurately diagnose sleep-disordered breathing in children.

Methods

The study consisted of a series of three tests, involving 24 patients and compared the Nellcor N-200 and N-395 with the Masimo SET v2 (Q-400™) and Masimo SET v3 (Radical) pulse oximeters. Up to 30 pulse oximetry desaturation events were randomly selected per subject. These desaturations were delineated as true, false or missed by use of the computerized polysomnograph or apnea parameters, which included a transcutaneous oxygen probe as a referee for true hypoxemia "events".

Results

The Masimo SET pulse oximeters captured 90% (v2) and 99% (v3) of the true desaturations, while the Nellcor devices captured 76% (N-200) and 45% (N-395). Notably, the Nellcor N-395 was 2.4 times more likely than the Masimo SET oximeter to report false desaturations during patient movement. The researchers offered a clinical caution. "On such abbreviated tests, clusters of movement-related artifactual desaturations could lead the physician to the mistaken impression of sleep-related desaturation events with the potential for unnecessary diagnostic testing or even inappropriate surgery."

	True Hypoxemia Detection
Masimo SET v3	99%
Masimo SET v2	90%
Nellcor N-200	76%
Nellcor N-395	45%

Authors' Discussion and Conclusions

The researchers completed their quest to find a replacement for the N-200 with the affirmation, **"In a pediatric sleep laboratory, use of a Masimo oximeter with very short averaging time could significantly reduce workload and improve reliability of desaturation detection."** More pointedly, they warned that, **"The sensitivity and motion artifact rejection characteristics of the Nellcor N-395 are not adequate for a pediatric sleep laboratory setting."**

105 "Motion-Resistant" Pulse Oximetry: A Comparison of New and Old Models

Barker SJ. *Anesthesia and Analgesia* 2002;95:967-72

Introduction

In previous studies, this researcher compared the performance of several pulse oximeters during mechanically controlled persistent motion and hypoxemia.[1,2] In this study, using the same test protocol, he studied all commercially available motion resistant pulse oximeters along with numerous conventional pulse oximeters during reduced perfusion and mechanically controlled motion (both periodic and random) on volunteers breathing room air and hypoxic gas mixtures.

Methods

Seventy (70) healthy volunteers participated in this study, with IRB approval and informed consent. Each subject was monitored with 6 oximeter sensors: three on digits 2,3, and 4 of the moving "test" hand and 3 of the same make and model on the digits of the non-moving "control" hand. The room temperature was reduced to 16° - 18° C to decrease peripheral perfusion. The test hand motions were achieved in a standardized, repeatable fashion by a computer-driven motion table. Tapping and rubbing motions at both fixed and randomly varied frequencies were studied. Data were recorded during various motions while subjects breathed room air, and during rapid arterial desaturation to SpO_2 - 75%. During the room air studies, 2 minutes of data were recorded for 2 motions: 1) fingers tapping at 3 Hz or at a frequency that varied randomly between 1 and 3 Hz and 2) fingers rubbing at these same frequencies. Once the two motions were completed and all SpO_2 values returned to baseline, the sensors were moved to different test fingers and the series was repeated twice, so that all 3 test digits were monitored with each test pulse oximeter. The protocol during hypoxemia included the addition feature of disconnecting and reconnecting (DC/RC) all test sensors after the motion had begun. The hypoxemia series was as follows: 1) non-motion hypoxemia to assess differences in instrument, limb, and finger response times; 2) random tapping motion with DC/RC at start of hypoxemia; 3) 3 Hz tapping motion with DC/RC at start of hypoxemia; 4) 3 Hz tapping during hypoxemia; and 5) random rubbing without DC/RC during hypoxemia. This series was performed once with each subject. Test and control SpO_2 values were compared in terms of sensitivity and specificity. Sensitivity measured a pulse oximeter's ability to detect a true desaturation, and specificity measured the pulse oximeter's likelihood of not generating false alarms during motion. An SpO_2 of 90% was chosen as the low alarm threshold. An SpO_2 performance index (PI) and pulse rate performance index along with drop out rate were calculated for each pulse oximeter. The SpO_2 PI measured the percentage of total time the displayed SpO_2 was within 7% of the control, and the PR PI measured the percentage of total time the pulse rate was within 10% of the control. The drop out % measured the total time the SpO_2 displayed was either zero or dashes.

Author's Discussion and Conclusion

"In summary, our volunteer data provide strong evidence that newer-generation pulse oximeters exhibit improved performance during patient motion. In particular, the Masimo SET appears to provide superior performance during patient motion, with substantially higher values of PI, sensitivity, and specificity." "The clinical implications of this performance improvement are significant. Because awake, hypoxic patients tend to be agitated and moving, pulse oximeters are more likely to be affected by motion artifact when the patient is in distress. Motion-resistant or read-through-motion oximeters, particularity the Masimo, will be more capable of displaying accurate SpO_2 values in this setting, which will improve our ability to detect life-threatening hypoxemia."

1. Barker SJ, Shah NK. The effects of motion on the performance of pulse oximeters in volunteers. *Anesthesiology* 1997;86(1):101-108
2. Barker SJ. The performance of six "motion-resistant" pulse oximeters during motion, hypoxemia, and low perfusion in volunteers. *Anesthesiology* 2001;95:A587

Results

Pulse oximeter	SpO_2 Performance Index	Pulse Rate Performance Index	SpO_2 sensitivity	SpO_2 specificity	Dropout rate (%)	Bias (%)	Precision (%)
Masimo SET® (v2)*	94	85	98	93	0.2	-0.41	2.98
Philips Viridia 24 C (Rev B.0)*	84	75	78	90	1.6	-1.52	4.51
Philips CMS (Rev B.0)*	80	73	70	83	3.7	-1.87	5.96
Datex-Ohmeda 3740	80	11	68	80	0.0	-2.33	4.20
Datex-Ohmeda 3800	79	12	63	77	0.7	-2.24	4.17
Datex-Ohmeda AS/3	77	67	90	45	0.2	-3.73	5.30
Nellcor N-395 (v 1620)*	71	47	66	78	4.1	-3.17	5.44
Datex-Ohmeda 3900	68	12	60	52	1.0	-3.20	4.22
Novametrix MARS (2000-10)*	58	27	40	42	2.4	-4.42	5.39
Hewlett-Packard CMS	57	20	63	30	0.5	-8.52	7.11
Nellcor N-180	57	15	35	43	3.1	-5.90	5.95
Marquette 8000	55	27	40	45	0.2	-6.22	6.68
Nellcor NPB-295	55	16	39	53	8.0	-5.79	6.21
Novametrix 520A	54	11	35	30	0.7	-5.03	5.07
Nellcor N-200	53	19	53	43	0.8	-7.18	5.97
BCI 3304	53	10	28	25	1.2	-7.38	5.74
Nonin 8600	48	13	45	18	1.4	-6.19	5.67
SpaceLabs 90308	46	40	40	23	0.8	-9.50	6.89
Nellcor NPB-190	43	16	48	33	11.1	-9.41	6.07
Criticare 5040	27	5	30	15	5.4	-12.64	6.44

* indicates pulse oximeters, which claim "motion resistance"

Table 1. Pulse oximeters are listed in descending order of SpO_2 performance index, which is the percentage of time the pulse oximeter displays an SpO_2 within 7% of control.

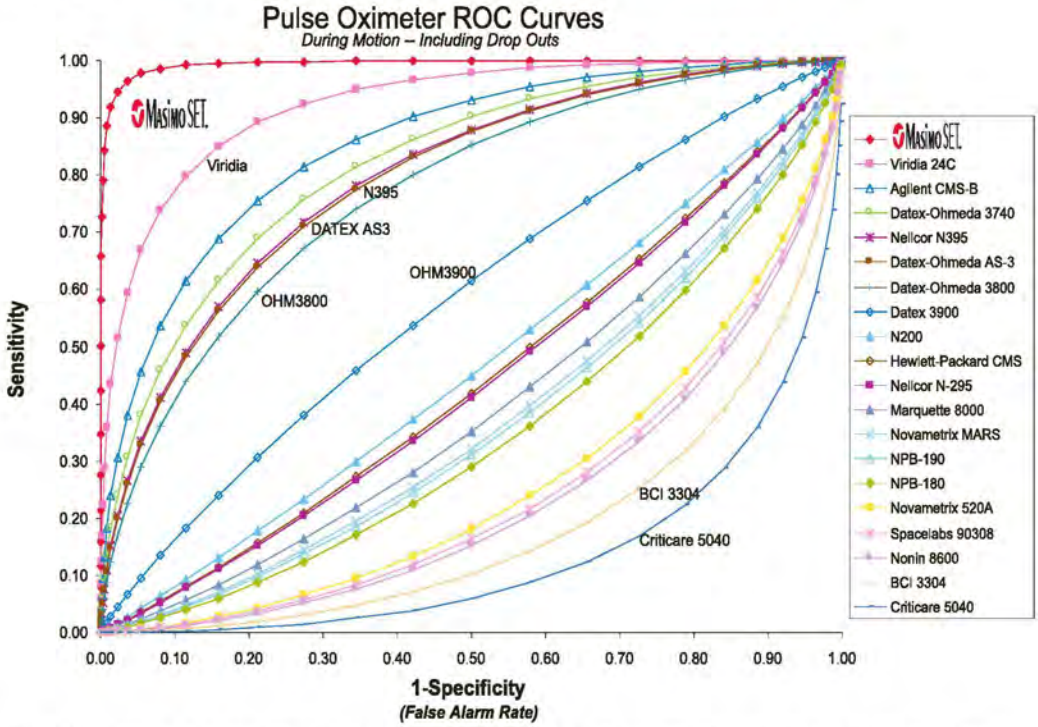


Figure 1. Receiver operating characteristic (ROC) curves calculated for 20 pulse oximeters in this study. The best-performance ROC curves lie in the upper left corner. Diagnosis of hypoxemia by a coin toss would produce an ROC curve along the line of identity, x=y.

110 Advantages of New Technology Pulse Oximetry with Adults in Extremis

Durbin CG, Rostow SK. *Anesthesia and Analgesia* 2002;94(S1):S81-S83

Introduction

Patient safety and human error factors, particularly latent errors, are a major concern in the delivery of health care today. Pulse oximetry is a critical monitor, which has been shown to fail in many critical situations. Oximetry failures can lead to potentially adverse patient outcomes. Failure to acquire and maintain reliable oximetry signals also increases the costs by necessitating more costly and invasive testing such as ABG analysis. The authors "chose to test the ability of the Masimo SET (MSO) technology, to acquire and maintain reliable pulse oximetry signals in critically ill, postoperative patients in whom conventional pulse oximetry (CPO) technology was unable to provide reliable monitoring."

Methods

The authors prospectively evaluated MSO in their thoracic and cardiovascular postoperative (TCVPO) unit. Patients were enrolled if clinicians were unable to acquire a reliable pulse oximetry signal using CPO (Ohmeda 3740). Immediately following failure of CPO, an oximeter incorporating Masimo SET technology was used to acquire a pulse oximetry signal. ABGs were obtained for validation of the SpO_2 and the pulse rate was confirmed with ECG heart rate.

Results

Thirteen postoperative cardiothoracic surgery patients (age range 53 - 81) were identified. In 12 of 13 (92.3%) patients who had failed CPO, MSO obtained pulse oximetry readings. The SaO_2 to SpO_2 difference was 1.1% + 1.0% (mean + SD) for these patients. In the patient in whom the authors were unable to obtain a MSO reliable value, they were also unable to obtain ABG data as the patient suffered cardiac arrest and required chest compressions.

SpO_2 measured in 13 patients with Masimo SET pulse oximetry, who had failed conventional pulse oximetry.

ABG (calculated) SpO_2 [%]	Masimo	CPO SpO_2 [%]	CPO Condition
99	100	0	Failed SpO_2
99	98	0	Failed SpO_2
97	98	0	Failed SpO_2
93	92	89	Failed PR (!)
99	99	Low Signal Quality	Failed SpO_2
98	98	Low Signal Quality	Failed PR (!)
(*)	Pulse Search	Low Signal Quality	Failed SpO_2
91	88	100	High SpO_2
98	98	0	Failed SpO_2
88	85	100	High SpO_2
94	93	82	Failed SpO_2
97	97	81	Failed SpO_2
95	97	Low Signal Quality	Failed SpO_2

(!) = lack of correlation for Pulse Rate and ECG heart rate, causing clinician to question SpO_2 accuracy

(*) = patient expired prior to obtaining arterial blood gas

Authors' Discussion and Conclusions

Causes of CPO failures are numerous. In this study population, CPO failure resulted from several factors including significant hypotension, poor peripheral perfusion, shivering due to hypothermia, and the presence of an intra-aortic balloon pump (IABP) producing an alteration of the arterial pressure waveform. Two patients in this study exhibited CPO SpO_2 values that were inaccurately high, even in these cases the MSO was able to obtain a reliable, accurate SpO_2 value. The impacts of monitor non-function are several. **Monitors providing no data or false alarms distract caregivers and require attention to troubleshoot the monitor. This decreases caregiver efficiency and increases costs. Ultimately, patient safety is affected. The authors conclude that the "ability of the MSO to provide reliable monitoring provides the bedside caregivers the ability to devote their time and attention to the patient and not to the monitoring system."** The 92.3% success rate in obtaining readings allowed for continuous, accurate monitoring of SpO_2 using the MSO in critically ill, unstable postoperative patients where CPO failed, thereby resulting in a significant increase in patient safety and caregiver efficiency."

115 Conversion to Masimo SET Pulse Oximetry - Analysis of Staff Satisfaction and Patient Safety Following Conversation

Lekites K, Jackvony R. *Respir Care.* 2002;47 (9): 1088.

Introduction

The process of a hospital converting to a new technology can be an onerous task for healthcare providers due to the duration of the installation process, the time required learning to utilize the new technology and in some cases unmet expectations as to the benefits of the new technology. For these reasons hospital staff may be reluctant to invest in new technologies. Contrary to these perceptions, several studies have documented the benefits of converting to Masimo SET pulse oximetry for the care of adult patients. Here, Lekites and Jackvony evaluate staff perceptions of Masimo SET pulse oximetry for the care of infants, following conversion of their Level II and Level III NICUs .

Methods

Twelve months after the conversion of the 60 bed, Level III NICU and the 16 bed Level II NICU to Masimo SET pulse oximetry, a survey was administered to the NICU clinical staff (RNs, RRTs) to evaluate staff satisfaction, clinical practice patterns and perceptions of patient safety. The survey questions allowed for a response of "Agree", Clinically no difference" or "Disagree" with each statement. Forty six clinicians responded to the survey. Chi-square analysis was used to test the distribution of results, with $p<0.05$ considered significant.

Results

n = 46 respondents	% Agree	% Disagree
Ease of application of the sensor	87	13
The combination of decreased false alarms and increased confidence in oximetry values has resulted in less distractions while caring for other infants	68	32
Changing to Masimo SET has resulted in less handling of infants to obtain reliable SpO_2 values	82	18
I have a greater sense of patient safety since changing to Masimo	81	19
Titration of delivered oxygen to the patient is easier since changing to Masimo	88	12
I have a greater sense of monitoring reliability since changing to Masimo	84	16
There has been less parental anxiety concerning false alarms and the reliability of the monitor since changing to Masimo	71	29
If I were transferred to another nursing unit, I would encourage conversion to Masimo oximetry	85	15

The results were significantly different from a random distribution with most respondents agreeing that the conversion to Masimo SET pulse oximetry resulted in greater staff satisfaction with patient monitoring and improved patient care and safety.

Authors' Conclusions

"After having used Masimo SET pulse oximetry in our NICU, our staff reports significant staff satisfaction and improved patient safety. They also perceive changes in their practice using this new technology, specifically in ease of management/titration of F_iO_2 levels. A significantly greater number of staff members agreed that they would recommend Masimo oximetry if they were transferred to another unit."

116 More Reliable Oximetry Reduces the Frequency of Arterial Blood Gas Analyses and Hastens Oxygen Weaning After Cardiac Surgery: A Prospective, Randomized Trial of the Clinical Impact of a New Technology

Durbin CG, Rostow SK. *Critical Care Medicine* 2002;30(8):1735-1740

Introduction

While pulse oximetry is an accepted standard of care, too few studies have analyzed its direct bearing on patient outcomes and clinical satisfaction. Among the complaints against pulse oximetry, high failure rates in monitoring the seriously ill, and high frequency of false alarms predominate. These researchers tested Masimo SET, a new, "innovative" technology claiming to have remedied the problems long associated with pulse oximetry, against an Ohmeda 3740, an oximeter deemed "conventional." Their general hypothesis was that improved oximetry would make a marked difference in patient outcome, while their specific hypothesis was that ventilator weaning and time to extubation would be reduced if caregivers were aided by truly innovative pulse oximetry.

Methods

A total of 89 patients undergoing coronary bypass surgery were monitored by both the conventional and the Masimo SET pulse oximeters, with sensors shielded and placed on the same hand. Data was recorded by both pulse oximeters, but clinicians were blinded to one of the pulse oximeters' readings, and were told only that they were taking part in a study on pulse oximetry. Times of pulse oximetry failure were recorded and used to compare "oximeter reliability," and clinical behavior was recorded and compared, including time to extubation, total weaning time, and arterial blood gas (abg) samples taken. When abgs were taken, the data was used by the researchers to calculate the bias and precision of both instruments according to Bland-Altman plots.

Results

The Masimo SET oximeter matched its claims.

a. Significantly fewer blood gases were taken.
b. Clinical trust was heightened and demonstrated by the choice to wean patients from high F_iO_2 more rapidly.
c. Fewer false alarms led to decreased clinical distractions.

Oximeter Used	Age, Yrs	Average Time to Extubation, Min ± SD	No. of ABGs to Extubation or F_iO_2= 0.4 ± SD	Average Time to F_iO_2= 0.4, Min ± SD	No. of Ventilator Changes to F_iO_2= 0.4 ± SD
Masimo SET	63 ± 12.9	634 ± 329	2.7 ± 1.2	176 ± 111	2.9 ± 1.2
Ohmeda 3740	64 ± 8.6	706 ± 459	4.1± 1.6	348 ± 425	2.9 ± 1.7
Significance, *p*	.827	.412	.000015	.0125	.908

Authors' Conclusion

"Presenting more reliable oximetry data to clinicians resulted in more rapid and efficient weaning of the F_iO_2, with fewer arterial blood gas measurements. This is all the more remarkable because clinicians were unaware of this arm of the study, and they had no independent knowledge of the improved reliability or accuracy of the [Masimo SET] device."

119 Influence of Pulse Oximeter Technology on Hypopnea Diagnosis Using the Newly Proposed Definition of a Respiratory Hypopnea.

Whitman RA, Garrison ME, Oestreich TJ. *Sleep* 2002; 25:A509.

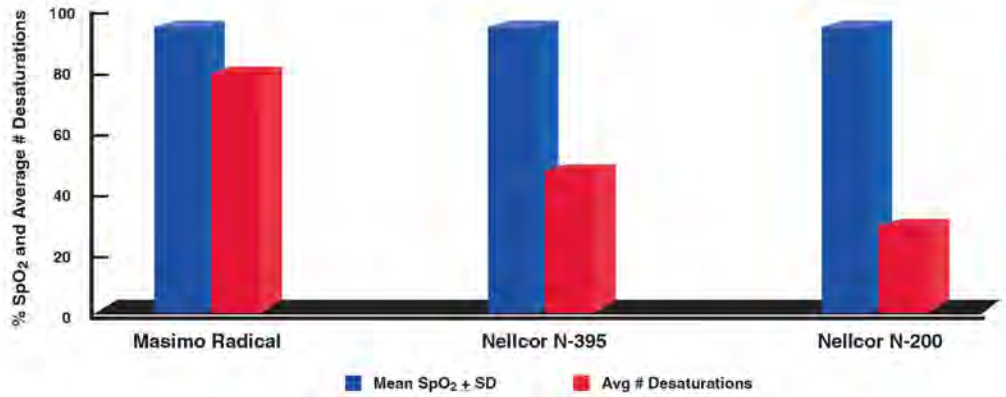
Introduction

Accurate tracking of transient desaturations is an important part of diagnosing obstructive sleep apnea (OSA) and for establishing Medicare coverage of continuous positive airway pressure (CPAP) therapy. The currently accepted definition for OSA, developed by the American Academy of Sleep Medicine Task Force in 1999[1] is an apnea-hypopnea index of at least 15 events/hour with hypopnea being a 4% or greater drop in oxygen saturation and a 30% reduction in airflow. In this study, Whitman and co-workers compared three pulse oximeters, the Masimo Radical, the Nellcor N-395 and the Nellcor N-200 to determine if the pulse oximeter technology could influence the scoring of desaturations in patients with possible sleep-disordered breathing.

Methods

Twenty-nine sleep lab patients with suspected sleep-disordered breathing were simultaneously monitored with three pulse oximeters, the Masimo Radical, the Nellcor N-395 and the Nellcor N-200, each set for the shortest averaging time. Trend data collected from the pulse oximeters was then downloaded onto a laptop computer for analysis with ProFox Oximetry Analysis software. Mean saturation and the number of desaturations greater to or equal to 4% SpO_2 were calculated and compared.

Results



Average SpO_2 and Average Number of Desaturations by Pulse Oximetry Technology in Sleep Lab Patients (n=29)

There was no difference in the mean SpO_2 readings between the three pulse oximeters. There was a large difference however, in the number of desaturations detected by the different technologies. The Masimo Radical detected 69% more desaturations than the Nellcor N-395 and 161% more desaturations than the Nellcor N-200.

Authors' Conclusions

There are serious health consequences to allowing OSA to go undiagnosed and untreated. Chronic or intermittent hypoxia, as occurs in patients with OSA and sleep disordered breathing, has been associated with numerous negative health consequences such as increased risk of heart failure, atrial fibrillation, stroke, high blood pressure, accidents and an overall decrease in quality of life.[2] The accurate diagnosis of OSA allows for more patients to receive CPAP treatment with coverage by Medicare. This study shows that, even when averaging times are similar, Masimo SET pulse oximetry is significantly better at tracking desaturations and therefore better for the diagnosis of OSA than other commonly used pulse oximetry technologies.

1. Sleep-related breathing disorders in adults: recommendations for syndrome definition and measurement techniques in clinical research. The report of an American Academy of Sleep Medicine Task Force. *Sleep.* 1999 Aug 1; 22(5):667-89.
2. Verneuil A, Marks JW. *Sleep Apnea.* MedicineNet.com 2005; Available at http:// www.medicinenet.com. Accessed 5/3/07.

120 The Pulse Oximeter Perfusion Index as a Predictor for High Illness Severity in Neonates

De Felice C, Latini G, Vacca P, Kopotic RJ. *European Journal of Pediatrics* 2002; 161:561-562.

Introduction

The perfusion index (PI) of a pulse oximeter is the pulsatile signal indexed against the non-pulsatile signal, expressed as a percentage (AC/DC X 100). Since this potential measure of peripheral perfusion does not require direct caregiver observation, which can be compromised by factors such as unpredictable skin coloration, its value as an assessment tool could be high. These researchers studied whether the perfusion index of the Masimo SET Radical could be used to assess the severity of neonatal illness.

Methods

Illness severity of 101 Caucasian infants was judged according to the Score for Neonatal Acute Physiology (SNAP) and each infant was placed into either the High Illness or Low Illness category. An operator who was unaware of the infant illness severity group captured PI values generated by a Masimo SET oximeter at regular intervals. SpO_2, pulse rate, body temperature, and blood pressure were also measured.

According to the predefined criteria, 43 neonates were admitted to the high severity group and 58 to the low severity group. The high severity group showed significantly higher severe neonatal morbidity. The receiver operating characteristic (ROC) curve was used to calculate the accuracy of the PI, SpO_2, and pulse rate in predicting high illness severity.

Results

SpO_2 and pulse rate showed insufficient accuracy in predicting illness severity, while the PI's predictive accuracy was shown to be significant, with 95.5% sensitivity, 93.7% specificity, 91.2% positive predictive value, and 96.8% negative predictive value.

	High Severity (43 neonates)	Low Severity (58 neonates)
PI*	0.86 ± 0.26	2.02 ± 0.70
SpO_2*	93.3 ± 5.4%	95.1 ± 3.9%
Pulse Rate*	139 ± 16 bpm	133 ± 17 bpm

*$p<0.0001$

Authors' Conclusion

"The results of the present study indicate that PI provides an unambiguous value, is not affected by the factors typically associated with subjective interpretation, and can provide easy, noninvasive and unattended monitoring of illness severity in neonates."

121 Detection of Hyperoxaemia in Neonates: Data from Three New Pulse Oximeters

Bohnhorst B, Peter CS, Poets CF. *Archives of Disease in Children Fetal Neonatal Ed* 2002;87:F217-F219

Introduction

The researchers objective was to investigate the ability of new generation pulse oximeters to detect hyperoxemia by maintaining a high degree of sensitivity [ability to detect hyperoxemia (too much oxygen in the blood)] while maintaining an acceptable level of specificity (ability to not falsely indicate hyperoxemia) while monitoring neonates. Reliable detection of hyperoxemia in neonates is important in minimizing the risks of acute and chronic oxygen toxicity, such as Retinopathy of Prematurity (infant eye disease or blindness).

Methods

Fifty-six (56) term and preterm infants were enrolled in the study. The median age at time of study was six (6) days (range 1 - 149) and the median study weight was 2680 g (range 430 to 5800). Pulse oximeters used in the study were the Masimo SET, Philips (Agilent) Viridia, and Nellcor Oxismart. The sensors used were the Masimo LNOP Neo PT and the Nellcor N-25 for the Philips and Oxismart pulse oximeters. In addition to standard monitoring equipment, 46 infants had one and 10 infants had two additional sensors attached to a hand and/or foot; the clinical characteristics of the infants in these subgroups were similar. Whenever an arterial blood sample was taken for clinical reasons, the SpO_2 readings on the pulse oximeters were recorded (the SpO_2 had to be stable for 20 seconds prior to blood draw). PaO_2 was measured on a Radiometer ABL 505 blood gas analyzer and functional SaO_2 was measured with a Radiometer OSM-3 CO-Oximeter.

Results

A total of 280 SpO_2/SaO_2/PaO_2 determinations were performed for the Philips (Agilent) Viridia, and 291 each for the Masimo SET and Oxismart pulse oximeters, with 105 (112 for Philips) in 27 (24) patients showing a PaO_2 > 80 mm Hg. Bias and precision (SaO_2 - SpO_2) calculations were: Masimo SET -0.06 ± 2.5%, Philips Viridia -0.25 ± 2.5, Nellcor Oxismart -0.91 ± 2.6%. The table below shows sensitivity and specificity at an upper alarm limit of 95%. The specificity for the Masimo SET pulse oximeter was 73% greater than the Nellcor Oxismart, and 50% greater than the Philips/Agilent Viridia technologies. NOTE: at this upper limit for SpO_2 the Masimo SET pulse oximeter had comparable specificity as the laboratory CO-Oximeter (OSM-3).

Upper Alarm Limit of 95%	Radiometer OSM- 3	Masimo SET	Philips Viridia	Nellcor Oxismart
Sensitivity	99	94	93	95
Specificity	46	45	30	26

Authors' Discussions and Conclusions

The authors stated, "Sensitivity can be increased by decreasing the upper alarm limit, but the specificity, which is already low, will then decrease even further. This carries the risk of keeping infants hypoxemic if priority is given to the avoidance of hyperoxemia." They concluded, "With regard to specificity, the MaS [Masimo SET oximeter] seemed to perform better than the other two instruments, which may be related to differences in measurement bias. Although these differences were small (< 1%), they may still be relevant, as small changes in SaO_2 may be associated with large changes in PaO_2 in the hyperoxic range."

122 Reliability of Conventional and New Pulse Oximetry in Neonatal Patients

Hay WW, Rodden DJ, Collins SM, Melara DL, Hale KA, Fashaw LM. *Journal of Perinatology* 2002; 22:360-366

Introduction

Pulse oximetry is widely used in the Neonatal Intensive Care Unit (NICU), however, clinicians often distrust the displayed SpO_2 and pulse rate (PR) values (particularly during patient motion) and are frustrated by the associated incidence of false alarms and inability to detect hypoxemia and bradycardia events.

Methods

The authors compared a Masimo SET pulse oximeter to one conventional (Nellcor N-200) and three claimed new generation pulse oximeters (Nellcor N-395, Novametrix MARS and Philips Viridia 24C Rev B.0). They studied a total of 33 non-sedated NICU infants (26 for Masimo vs. N-200 and 7 for Masimo vs. new generation) who were on supplemental oxygen and/or mechanical ventilation. ECG heart rate, SpO_2 and PR were captured by a computer PC for a total of 184 hours.

Results

Compared with the new generation pulse oximeters, false desaturations, data dropouts, and false bradycardias were lowest for Masimo SET, while the capture of true desaturations and bradycardias was highest for Masimo SET. Notably, the new generation devices differed greatly in their ability to detect changes in PR (i.e., an acute change in ECG HR > 25 bpm). See table below for these results. Compared with the Nellcor N-200, Masimo SET had 86% fewer false alarms, which also were shorter in duration, resulting in 92% less total alarm time. Masimo SET also identified 12 of 14 bradycardias (86%) vs. 2 of 14 (14%) for the N-200 (26 patients).

	Masimo SET®	Nellcor N-395	Novametrix MARS	Philips / HP Viridia Rev. B.0
"False" Hypoxemia	1	42	33	10
Missed Desaturations	1	4	12	6
"False" Bradycardia	1	1	61	2
Frozen Pulse Rate	0	6	46	11
Data Drop-out	1	10	93	21

Authors' Discussion and Conclusions

"Masimo SET pulse oximetry recorded markedly fewer false SpO_2 and PR alarms and identified more true hypoxic and bradycardic events than either a conventional or three other new generation pulse oximeters. Decreased false alarming should benefit the infant's behavioral state and improve the caregiver's response to monitoring a vital parameter. Improved confidence in SpO_2 and heart rate changes could reduce clinician stress. The missed detection of changes in heart rate by some new generation pulse oximeters is worrisome. **Routine use of Masimo SET should improve clinician confidence leading to more accurate administration of oxygen with possible reductions in hypoxic (e.g., pulmonary hypertension) and hyperoxic (e.g., retinopathy of prematurity) pathology."**

127 Patient Safety and Staff Satisfaction Following Conversion to Masimo SET Pulse Oximetry - Experience in the Neonatal ICU

Noblet T. *Respiratory Care* 2001;46(10):1140

Introduction

This study evaluates the patient safety and staff satisfaction following a unit wide conversion to Masimo SET pulse oximetry technology. Recent reports highlight the importance of human and system error on patient safety.[1] In addition, to the stress placed on staff and the resultant latent errors, monitor function causes other problems in the Neonatal ICU (NICU) with noise from alarms as well as increased handling of the infants to obtain reliable monitoring signals.[2,3] It has been demonstrated that even minor changes in noise and activity in the NICU can affect infant's physiology and well being.[3] The impact of a new oximetry technology on staff perception of patient safety and stress levels was evaluated.

Methods

All oximetry technology in their 39 bed level III NICU was converted to Masimo SET oximetry. Following the conversion a survey was developed to assess factors related to patient safety and staff satisfaction and was administered to RNs, RRTs and MDs in their NICU, 23 clinicians responded. Questions were designed for clinicians to respond to each with either "disagree" or "not disagree" with the statement. The following questions were asked: (1) The noise level in the Nursing unit is reduced now compared to before conversion to Masimo oximetry, (2) Changing to Masimo oximetry has resulted in less handling of infants to "fix or adjust" sensors in order to obtain reliable saturation values, (3) I have a greater sense of patient safety since changing to Masimo oximetry, (4) The combination of decreased false alarms and increased confidence in oximetry values has resulted in less distractions while caring for other infants, (5) I have a greater sense of monitoring reliability since changing to Masimo oximetry, (6) The combination of decreased false alarms and increased confidence in oximetry values has resulted in a reduction in staff stress levels, (7) Since changing to Masimo oximetry there has been less parental anxiety concerning the frequency of false alarms and the reliability of the monitor, (8) If I were to transfer to another nursing unit, I would encourage that unit to use Masimo oximetry. Chi-square analysis was used to test the distribution of results, $p < 0.05$ was considered significant.

Results

The results of this survey are tabulated below. These results were significantly different from a random distribution, $p < 0.001$.

Question number	1	2	3	4	5	6	7	8
% not disagree	70%	96%	91%	83%	83%	74%	78%	83%

Authors' Discussion and Conclusion

"After having used Masimo SET pulse oximetry in our NICU, **our staff perceived greater patient safety and staff satisfaction from this new technology.** A significantly greater number of staff members agreed that Masimo oximetry technology offers improved patient safety by agreeing with questions 2 - 5, which were directed at improved patient safety. **A significantly greater number of staff members agreed that they would recommend Masimo oximetry if they were transferred to another unit."**

1. Kohn LT, Corrigan JM, Donaldson MS, Editors. *Institute of Medicine*, National Academy Press, 1999.
2. Ahlborn V, Bohnhorst B, Peter CS, Poets CF. *Acta Paediatr* 89:571-576, 2000.
3. Slevin M, Farrington N, Duffy G, Daly L, Murphy JFA. *Acta Paediatr* 89:577-581, 2000.

129 Cost Reduction Following Conversion to Masimo SET Pulse Oximetry – Experience in the Neonatal ICU.

Noblet T. *Respir Care* 2001 46(10): 1130.

Introduction

There are very few published studies that compare the costs of utilizing different pulse oximetry technologies even though patient monitoring represents significant hospital expenditure. Since adhesive sensor use represents the greatest recurring expense to utilizing pulse oximetry, Noblet compared the cost associated with using Criticare adhesive sensors (pre-conversion) to using Masimo SET adhesive sensors (post- conversion), in the 39 bed level III NICU at St Vincent Hospital in Indianapolis, IN.

Methods

A retrospective analysis was performed to determine if there was a difference in the number of sensors used per patient prior to the hospital's conversation from Critcare pulse oximetry to Masimo SET pulse oximetry. The number of sensors utilized per patient admission, the length of stay and the average number of patients, daily for a three month period prior to the conversion to Masimo SET pulse oximetry was compared to the sensors used per patient for the three months following the conversion. All patients admitted to the NICU were monitored with pulse oximetry during both periods.

Results

Sensor utilization per patient in the NICU pre and post conversion to Masimo SET Pulse Oximetry.

	# of Admissions	Average Daily # Patients	# of Sensors Used	# Sensors used per Admission	Sensor Longevity (days)
Criticare	213	32.7	544	2.6	4.8
Masimo SET	265	38.1	400	1.5	11.5

Although the number of admission and the average daily census increased during the three month period following the conversion to Masimo SET, the total number of sensors used decreased. An NICU staff survey found that 83% thought that Masimo SET sensors were superior to the Critcare sensors and 96% reported that the Masimo sensors required less handling of patients to obtain reliable saturation readings.

Authors' Conclusions:

"Conversion to Masimo oximetry has resulted in a 58% reduction in sensor consumption in our NICU. Masimo sensors lasted 11.5 days, on average, which is approximately 2.4 times as long as the Criticare sensor. In our experience Masimo oximetry sensors significantly reduce the cost of oximetry monitoring. We attribute this to their increased durability and ease of acquiring initial oximetry readings."

135 More Reliable Oximetry Improves Caregiver Efficiency

Durbin CG, Rostow SK. *Anesthesiology* 2000:93:ASCCA suppl., B14

Introduction

The authors' hypothesis was that monitors requiring frequent attention to maintain or verify their accuracy would divert caregivers from other tasks, decreasing efficiency, and increasing cost of care. Likewise, improved monitor accuracy should improve caregiver efficiency and this improvement should be measurable.

Methods

To test the hypothesis, the researchers prospectively evaluated the effects on caregiver activities and patient outcome of two pulse oximetry technologies (Masimo SET and Datex-Ohmeda 3740, the product used by the hospital at the time of the study) on 48 patients post CABG during their ICU period. One of the oximeters was randomly selected to provide the displayed saturation for bedside care ("unblinded" condition). Clinicians were unaware of data from the other oximeter ("blinded" device). No other clinical management processes or protocols were altered for this study. Recording was continued until 4 hours following tracheal extubation or for a maximum of 24 hour. They determined the "down time" in total minutes for each monitor (reported as a percentage of non-functional time, or NFT), the time to weaning of F_iO_2 to 0.40, time to extubation, number of ventilator changes, and the number of ABGs obtained during weaning. Data was reported and analyzed separately when the output of the device was "blinded" or "unblinded" to the caregiver.

Results

The percent of Non-Functional Time (NFT) for the Masimo SET device was significantly less in both cases, when blinded and unblinded to the caregiver, compared to the conventional pulse oximeter device. There were significantly fewer ABGs and the time to F_iO_2 was significantly less when the Masimo SET device was relied upon instead of the conventional pulse oximeter.

Marker	Masimo SET®	CPO	Significance
Unblinded % NFT	0.3 ± 0.4%	5.4 ± 6.6%	p = 0.02
Blinded % NFT	0.4 ± 0.6%	6.6 ± 8.1%	p = 0.02
ABG's / patient	2.0 ± 0.9	3.4 ± 1.6	p = 0.03
Minutes to 40% O_2	135 ± 68	232 ± 130	p = 0.04

Authors' Discussion and Conclusions

The researchers concluded that caregivers had more confidence in the data from Masimo SET compared to the conventional pulse oximeter and this resulted in fewer unnecessary diversions in their care patterns. **"The use of a pulse oximeter employing Masimo SET resulted in significantly less down time, more rapid weaning of F_iO_2 and fewer ABGs than a conventional pulse oximeter when used in ICU patients following cardiac surgery."**

2000 Best ASA Abstract Presentation, Society for Technology in Anesthesia.

140 Weaning Protocol Possible with Pulse Oximeter Technology

Patel DS, Rezkalla R. *Advance for Managers of Respiratory Care* 2000;9(9):86

Introduction

Managed care protocols are critical to the efficient practice of medicine. Physiologic endpoints can be used as targets for guiding the care paths taken in a variety of settings. Monitoring site hypoperfusion and motion artifact are a common source of problems with pulse oximetry monitoring for patients in an intensive care unit (ICU). The typical result of such conditions is an under estimation of the correct SpO_2. These errors are especially problematic in patients during weaning from mechanical ventilation and could prolong the process while the clinician verifies the patient's oxygenation status through other means, e.g., clinical assessment or blood gases. More reliable pulse oximetry should reduce weaning delays thereby reducing the time and associated costs of mechanical ventilation.

Methods

A mechanical ventilation weaning protocol was implemented in the multi-purpose ICU of a 130-bed community hospital. The patient and caregivers outcomes were compared before and after a change in pulse oximeter technology (from use of the Invivo 4500+ and Ohmeda 3700 to that of Masimo SET contained in an MDE Escort Prism monitor). Nine months of data was reviewed.

Results

"We reported the following evidence of decreased costs and improved patient outcomes:

- decreased oxygen requirement and usage
- 40% reduction in mechanical ventilation hours/patient
- significant reduction in frequency and quantity of ABG's drawn
- 42% reduction in length of stay (from 5.3 to 3.1 days)"

Authors' Discussion and Conclusions

"Because the ABG's consistently correlated with the pulse oximeter, the RT's grew confident with the readings. The number of ABG's declined, and the weaning times became faster. We are delighted with the results." Masimo SET pulse oximetry proved successful to a care protocol for weaning patients from mechanical ventilation. Caregiver confidence, mechanical ventilation weaning time, patient length of stay and costs associated with ICU care all declined. This success was found when older Invivo and Ohmeda pulse oximetry was replaced with Masimo SET contained in an MDE Escort Prism monitor.

152 Pulse Oximetry in Transport of Poorly-Perfused Babies

Goldstein MR, Liberman RL, Taschuk RD, Thomas A, and Vogt JF. *Pediatrics* 1998;102(3):818

Introduction

Poor perfusion and monitoring site motion can adversely affect pulse oximetry readings. This short coming worsens during patient transport in that the motion component is both innate and imposed. The degree of monitoring error can be so great as to render the output meaningless on the most acutely ill (a zero, dashed lines or a spurious % SpO_2 value is displayed). The paradox of conventional pulse oximetry has been that in those patients where continuous monitoring of oxygenation status would be most beneficial, their condition (physiology and environmental) can foil the measurement. Persistent Pulmonary Hypertension of the Newborn (PPHN) is a condition where venous blood mixes with systemic. If the peripheral pulsations are great enough and not confounded by artifact, the shunt can be detected by differential pulse oximetry (right arm versus any other extremity). Masimo has developed a unique sensor design and software algorithms designed to identify the % SpO_2 and pulse rate regardless of patient or environmental challenges. In particular, helicopter transport of acutely ill subjects has been associated with reports of pulse oximeter failures with various models from multiple manufacturers of conventional pulse oximeters.

Methods

Five infants, all with documented cardiac shunting due to PPHN and transported via helicopter, comprised the study population. All infants were acutely ill and referred for extracorporeal membrane oxygenation (ECMO) or inhaled nitric oxide (INO) therapy. The effect of motion and low peripheral perfusion (variable cardiac shunt) on the reliability of two pulse oximeters (a conventional-type, the Nellcor N-200, and a new Masimo-based unit) were evaluated.

Results

The pulse oximeters were functional on every infant prior to transport. However, both imposed motion and low perfusion were responsible for failures to read by the pulse oximeters. % SpO_2 readings were evaluated in terms of failure rate (number of failures/number of total data points). Failures were defined as a pulse oximeter display of zero or any SpO_2 value where the oximeter pulse rate and ECG heart rate were not within 5 beats/minute. A large and significant difference in failure rate was found between the two manufacturers.

	Masimo SET®	Nellcor N-200
Failure Rate due to Helicopter Takeoffs/Landings	0%	100%
Failure Rate due to Low Perfusion	5%	74%

Authors' Discussion and Conclusions

"Access to the continuous output of post-ductal oximetry was extremely valuable to the clinical management of PPHN during transport. **Pulse oximetry with Masimo SET has dramatically fewer failures than conventional pulse oximetry during interhospital transport of poorly perfused infants."**

1998 Science Award, Foundation for Air Medical Research

153 Left Heart Hypoplasia: A Life Saved With the Use of a New Pulse Oximeter Technology

Goldstein MR. *Neonatal Intensive Care* 1998;12(1):14-17.

Introduction

When symptomatic, hypoplastic left heart syndrome causes congestive heart failure and circulatory collapse, the initial diagnosis and quick treatment can be a challenge to the most proficient caregiver. On initial exam, they are in respiratory distress, pale and moribund with weak pulses (often beyond palpation). This lesion, if undetected, is rapidly lethal with surgical intervention providing the only hope of survival.

Case Study Initial Findings

In 1995, a nine-day old infant was brought to the emergency department of a regional medical center. The child was pale, had a thready pulse, and circumoral cyanosis was evident. A Nellcor pulse oximeter was placed at multiple sites but no reading was acquired. Repeated attempts to obtain arterial blood gas specimen failed due to profound hypotension.

Case Study Results

Upon arrival of a neonatologist, the infant was tracheally intubated and hand ventilated with 100% oxygen. A cut-down provided umbilical artery access and several blood gases followed over the next five hours (see table). The neonatologist attempted, without success, to obtain a reliable signal with a Nellcor pulse oximetry and (after parental consent) resorted to a prototype Masimo pulse oximeter. Immediate values of saturation in the low 30's and pulse rate in the 40's resulted. The Masimo SET device continued to display during the following two critical hours of resuscitation and stabilization with the SpO_2 and pulse rate values corroborated by blood gases and the ECG heart rate. "The Nellcor pulse oximeter did not function at all during this period." Further workup revealed a hypoplastic left ventricle for which the child was medically stabilized, received a cardiac transplant eight days later and survives today.

Blood Gases Taken in the 1st Five Hours of Resuscitation

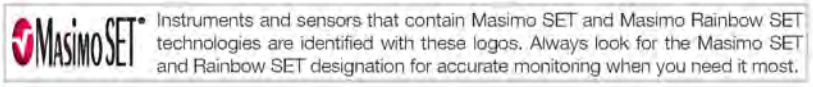
pH	$PaCO_2$	PaO_2	Base Deficit
6.56	88	29	off scale
6.73	98	36	off scale
6.88	61	23	26.2
7.07	35	65	-20.6
7.24	31	64	-18.2
7.42	36	43	-0.6

Author's Discussion and Conclusions

If untreated, left heart hypoplasia is fatal. A rapid response to the inevitable circulatory collapse is vital. A conventional pulse oximeter did not work in this situation. Whereas, Masimo SET pulse oximetry provided accurate, real-time data during resuscitation and stabilization of an infant with hypoplastic left heart syndrome. **"Were it not for the steady rise in % SpO_2 values, the resuscitative efforts for this baby would have been aborted. This newborn's life was likely saved by Masimo SET pulse oximetry."**

NOTES

NOTES



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